TITLE 105 INDIANA DEPARTMENT OF TRANSPORTATION

LSA Document #01-374(F)

DIGEST

Amends 105 IAC 9-4 concerning current categories for business logo signs and adds qualifications for a new category of business logo signs. It will also add a fee for seasonal installation and removal of closed panels, a requirement of compliance checks and notice of violations, and the consideration of available space when locating signs. The rule will also make other substantive and technical changes for spacing requirements for signs and will establish a timeframe for conformance with the spacing requirements. Effective 30 days after filing with the secretary of state.

105 IAC 9-4-4
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105 IAC 9-4-13

SECTION 1. 105 IAC 9-4-4 IS AMENDED TO READ AS FOLLOWS:

105 IAC 9-4-4 Definitions
Authority: IC 8-23-2-6
Affected: IC 9-21-4-5

Sec. 4. As used in this rule:

~~(1) "Business sign" means a separately attached sign mounted on specific information panels to show the brand, symbol, trademark, or name, or combination of these, for a motorist service available at or near an interchange.~~

(1) "Business facility" means a business operating in one (1) or more of the areas of service permitted for installation of specific service signs and meeting the criteria for installation of a logo panel.

(2) "CLOSED panel" is a panel imprinted with the word CLOSED that may be installed over a logo panel to indicate the seasonal closing of a business.

~~(2)~~ **(3)** "Contractor" means the individual, partnership, firm, corporation, or combination of same contracting with the department for performance of prescribed work.

~~(3)~~ **(4)** "Department" means the Indiana department of transportation.

~~(4)~~ **(5)** "Freeway" means a divided highway for through traffic with full control of access.

~~(5)~~ **(6)** "Full control of access" means the condition where the right of owners or occupants of abutting land or other persons, to access light, air, or view in connection with a highway is fully controlled. Full control is exercised to give preference to through traffic by providing access connections only with selected public roads and by prohibiting crossings at grade or direct private driveway connections.

(7) "Interstate system" means the federally designated system of interstate highways with full control of access.

(8) "Logo panel" is a business sign and means a separately attached sign mounted on specific service signs to show the brand, symbol, trademark, or name, or combination of these, for a motorist service available at or near an interchange.

(9) "Miniature logo panel" means a reduced size duplicate of the logo panel installed on the specific service sign in advance of the interchange which is installed on the specific service ramp sign.

(10) "Primary applicant" means a business facility requesting a logo panel which meets the highest standard for the specific service.

(11) "Secondary applicant" means a business facility requesting a logo panel which meets a reduced standard for the specific service. Contracts for secondary applicants may be for a shorter period than for primary applicants.

~~(6)~~ **(12)** "Specific ~~information panels"~~ **service sign" is a specific information panel and** means a rectangular sign panel with the following:

(A) The words "GAS", "FOOD", "LODGING", ~~or~~ "CAMPING", **or "ATTRACTION".**

(B) Directional information.

(C) One (1) or more ~~business signs.~~ **logo panels.**

(13) "Specific service ramp sign" means a reduced size specific service sign installed on an interchange ramp to indicate distance and direction to a service facility not readily visible from the ramp intersection with the intersecting roadway.

(Indiana Department of Transportation; 105 IAC 9-4-4; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2326; filed Mar 2, 1988, 10:55 a.m.: 11 IR 2330; filed Jan 8, 1992, 12:00 p.m.: 15 IR 698; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2438) NOTE: Transferred from Department of Highways (120 IAC 4-5-4) to Indiana Department of Transportation (105 IAC 9-4-4) by P.L.112-1989, SECTION 5, effective July 1, 1989.

SECTION 2. 105 IAC 9-4-5 IS AMENDED TO READ AS FOLLOWS:

105 IAC 9-4-5 Costs; rental fee
Authority: IC 8-23-2-6
Affected: IC 9-21-4-5

Sec. 5. (a) The ~~specific service applicant~~ **business facility** or the department's contractor shall bear all costs of manufacturing, installation, and maintenance relating to their respective ~~business sign~~ **logo panel and miniature logo panel,** including theft, vandalism, or damage for any reason.

(b) The ~~specific service applicant~~ **business facility** shall pay a rental fee to the department or its authorized contractor.

(c) Business facilities which operate on a seasonal basis shall pay a fee for installation and subsequent removal of CLOSED panels or removal and reinstallation of logo panels.

~~(c)~~ ~~The~~ ~~rental~~ ~~fee~~ **(d) Fees** will be established or approved jointly by the department and the Indiana department of commerce. *(Indiana Department of Transportation; 105 IAC 9-4-5; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2326; errata, 7 IR 2546; filed Mar 2, 1988, 10:55 a.m.: 11 IR 2331; filed Jan 8, 1992, 12:00 p.m.: 15 IR 699; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2438) NOTE: Transferred from Department of Highways (120 IAC 4-5-5) to Indiana Department of Transportation (105 IAC 9-4-5) by P.L.112-1989, SECTION 5, effective July 1, 1989.*

SECTION 3. 105 IAC 9-4-6 IS AMENDED TO READ AS FOLLOWS:

105 IAC 9-4-6 Installation of panels; violations
Authority: IC 8-23-2-6
Affected: IC 9-21-4-5

Sec. 6. (a) Installation of a ~~business~~ ~~sign~~ **logo panel** shall be done by the department or its authorized contractor.

(b) The department, or its contractor, shall monitor business facilities on a regular basis, and may conduct random inspections, to assure continued compliance with the conditions of this rule.

(c) The department, or its contractor, shall notify any business facility found not in compliance with any condition of this rule and request compliance within a reasonable time period. Upon reinspection, if the business facility is not in compliance, the business facility shall be deemed in violation of this rule. After two (2) findings of noncompliance with subsequent return to compliance with the same condition of this rule, finding a third noncompliance shall be deemed a violation of a condition of this rule.

~~(b)~~ **(d)** The department, or its contractor, may remove ~~or place closed panels on,~~ any ~~business sign~~ **logo panel** for violation of any of the conditions of this rule.

(e) A business facility whose logo panel is removed for a violation of any condition of this rule may file as a new primary or secondary applicant. No preference will be granted for the prior installation of a logo panel. *(Indiana Department of Transportation; 105 IAC 9-4-6; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2327; errata, 7 IR 2546; filed Mar 2, 1988, 10:55 a.m.: 11 IR 2331; filed Jan 8, 1992, 12:00 p.m.: 15 IR 699; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2439) NOTE: Transferred from Department of Highways (120 IAC 4-5-6) to Indiana Department of Transportation (105 IAC 9-4-6) by P.L.112-1989, SECTION 5, effective July 1, 1989.*

SECTION 4. 105 IAC 9-4-7 IS AMENDED TO READ AS FOLLOWS

105 IAC 9-4-7 Location of specific service signs; general requirements
Authority: IC 8-23-2-6
Affected: IC 9-21-2; IC 9-21-4-5

Sec. 7. (a) ~~Business signs on specific information panels~~ **When the spacing requirements in section 10 of this rule can be met, specific service signs** may be erected along the interstate system and other freeways, except at the following locations:

(1) At an interchange where motorists cannot conveniently reenter the freeway and continue in the same direction of travel.

(2) Freeway to freeway interchanges.

(3) Interchanges where ~~business~~ **specific service** signs are inappropriate due to safety considerations.

(b) The specific ~~information panels~~ **service signs** should be located so as to take advantage of natural terrain, to have the least impact on the scenic environment, and to avoid visual conflict with other signs within the highway right-of-way. Unprotected **specific service** sign ~~panel~~ supports located within the clear zone shall be of a breakaway design.

(c) In the direction of traffic **flow,** successive specific ~~information panels~~ **service signs** shall be those for **"ATTRACTION",** "CAMPING", "LODGING", "FOOD", and "GAS" in that order.

(d) The department will designate, by official action, interchanges where ~~business~~ **specific service** signs may not be erected due to safety considerations. *(Indiana Department of Transportation; 105 IAC 9-4-7; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2327; filed Jan 8, 1992, 12:00 p.m.: 15 IR 699; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2439) NOTE: Transferred from Department of Highways (120 IAC 4-5-7) to Indiana Department of Transportation (105 IAC 9-4-7) by P.L.112-1989, SECTION 5, effective July 1, 1989.*

SECTION 5. 105 IAC 9-4-8 IS AMENDED TO READ AS FOLLOWS:

105 IAC 9-4-8 Specific information permitted
Authority: IC 8-23-2-6
Affected: IC 9-21-2; IC 9-21-4-5

Sec. 8. ~~(a) Each business identified on a specific information panel must give written assurance to the state, or the contractor, of its conforming with all applicable laws concerning the provisions of public accommodations without regard to race, religion, color, sex, or national origin, and must not be in breach of that assurance.~~

~~(b)~~ **(a)** The types of services signs permitted are "GAS", "FOOD", "LODGING", ~~and~~ "CAMPING", **and "ATTRACTION"** and only one (1) type of service per ~~business sign.~~ **logo panel.** To qualify for display on a specific ~~information panel,~~ **service sign,** the service facility must meet the requirements outlined in section 13 of this rule.

~~(c)~~ **(b)** The number of specific ~~information panels~~ **service signs** permitted is limited to a maximum of one (1) for each type of service **up to a maximum of four (4) specific service signs** along an approach to an interchange. The number of ~~business signs~~ **logo panels** permitted on a specific ~~information panel~~ **service sign** is specified in section 11 of this rule. *(Indiana Department of Transportation; 105 IAC 9-4-8; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2327; filed Mar 2, 1988, 10:55 a.m.: 11 IR 2332; filed Jan 8, 1992, 12:00 p.m.: 15 IR 699; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2439) NOTE: Transferred from Department of Highways (120 IAC 4-5-8) to Indiana Department of Transportation (105 IAC 9-4-8) by P.L.112-1989, SECTION 5, effective July 1, 1989.*

SECTION 6. 105 IAC 9-4-9 IS AMENDED TO READ AS FOLLOWS:

105 IAC 9-4-9 Size and design; composition; general specifications
Authority: IC 8-23-2-4.1; IC 8-23-2-6
Affected: IC 9-21-4

Sec. 9. (a) The specific ~~information panels~~ **service signs** shall have a blue **reflectorized** background with a white reflectorized border. The size of the specific ~~information panels~~ **service signs** shall not exceed the minimum size necessary to accommodate the maximum number of ~~business signs~~ **logo panels** permitted using the required legend height and the interline and edge spacing of current standards of the Indiana Manual on Uniform Traffic Control Devices.

(b) ~~Business signs~~ **Logo panels** shall have a blue background with white legend and border, except where standard business ~~signs~~ **identification symbols or trademarks** provide a background color. Signs shall be manufactured from sheet aluminum **(eighty-thousandths** (.080) inches thick) with reflective sheeting. The principal legend should be at least equal in height to the directional legend on the **specific service** sign panel. Where business identification symbols or trademarks are used for a ~~business sign,~~ **logo panel,** the border may be omitted. The symbol or trademark shall be reproduced in the color and general design consistent with customary use, and any integral legend shall be in proportionate size. Messages, symbols, or trademarks which resemble any official traffic control device or tend to direct traffic are prohibited. The vertical and horizontal spacing between ~~business signs~~ **logo panels** on ~~sign panels~~ **specific service signs** shall not exceed eight (8) inches and twelve (12) inches respectively.

(c) All directional arrows and all letters and numbers used in the name of the type of service and the directional legend shall be white and reflectorized. *(Indiana Department of Transportation; 105 IAC 9-4-9; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2327; errata, 7 IR 2546; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2440) NOTE: Transferred from Department of Highways (120 IAC 4-5-9) to Indiana Department of Transportation (105 IAC 9-4-9) by P.L.112-1989, SECTION 5, effective July 1, 1989.*

SECTION 7. 105 IAC 9-4-10 IS AMENDED TO READ AS FOLLOWS:

105 IAC 9-4-10 Location of signs; special requirements
Authority: IC 8-23-2-6
Affected: IC 9-21-2; IC 9-21-4-5

Sec. 10. (a) Except as provided in section 11(c) of this rule, a separate **specific service** sign ~~panel~~ must be provided for each type of service upon which ~~business signs~~ **logo panels** are displayed.

(b) The specific ~~information panels~~ **service signs** should be erected between **eight hundred (800) feet beyond the end of the last entrance taper of** the previous interchange and eight hundred (800) feet minimum in advance of the exit ~~direction sign,~~ **lane taper,** or the general motorist service sign if present, at the interchange from which the services are available. **When longitudinal space permits, all specific service signs should be installed before the one (1) mile exit panel.** There should **normally** be at least eight hundred (800) feet spacing between the signs, **and at least eight hundred (800) feet visibility to a sign installed beyond a sight obstruction.** Excessive spacing should be avoided.

(c) Specific service signs existing at the time this rule is adopted and not meeting these spacing requirements may remain in place for the remainder of their normal service life but no longer than fifteen (15) years from adoption of this rule. At the end of the service life or at some time before the fifteen (15) years limit is reached, signs not complying with these spacing requirements should be removed or relocated in compliance with these requirements.

(d) When available space or other restrictions limit the number of specific service signs that may be installed approaching an interchange, the order of preference for choosing services to be displayed shall be "GAS", "FOOD", "LODGING", "CAMPING", "ATTRACTION".

~~(c)~~ **(e)** At single-exit interchanges, where service facilities having a ~~business sign~~ **logo panel** are not visible from the ramp terminal, ~~miniature directional business sign panels~~ **specific service ramp signs** must be installed at the ramp terminal as follows:

(1) ~~Directional sign panels~~ **Specific service ramp signs** must include the distance and the directional arrow to the service facility.

(2) The installation of ~~miniature directional business sign panels~~ **specific service ramp signs** shall be at the expense of the business facility.

(3) The miniature ~~business sign~~ **logo panels installed on specific service ramp signs** must be ~~a duplicate of the corresponding specific business sign along the main roadway but reduced in size to~~ eighteen (18) inches high by twenty-four (24) inches wide. ~~The design of this sign must be approved by the department.~~

(4) The miniature ~~business sign~~ **logo panel** on the ~~directional~~ **specific service ramp** sign ~~panel~~ will be installed after receipt of the miniature ~~business sign~~ **logo panel** from the business facility.

(5) Miniature ~~business signs,~~ **logo panels,** if required, must accompany the specific ~~business signs~~ **logo panel** before any installations are made.

(Indiana Department of Transportation; 105 IAC 9-4-10; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2328; errata, 7 IR 2546; filed Mar 2, 1988, 10:55 a.m.: 11 IR 2332; filed Jan 8, 1992, 12:00 p.m.: 15 IR 700; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2440) NOTE: Transferred from Department of Highways (120 IAC 4-5-10) to Indiana Department of Transportation (105 IAC 9-4-10) by P.L.112-1989, SECTION 5, effective July 1, 1989.

SECTION 8. 105 IAC 9-4-11 IS AMENDED TO READ AS FOLLOWS

105 IAC 9-4-11 Design; special requirements

Authority: IC 8-23-2-6
Affected: IC 9-21-4

Sec. 11. (a) At single-exit interchanges, the name of the type of service followed by the exit number shall be displayed in one (1) line above the ~~business signs,~~ **logo panels,** or, as an alternate, the exit number may be placed above the specific ~~information panel~~ **service sign** and the type of service(s) should be displayed in one (1) line above the ~~business signs.~~ **logo panels.** At unnumbered interchanges, the directional legend "NEXT RIGHT (LEFT)" shall be substituted for the exit number. The specific ~~information panel~~ **service sign** shall be limited to six (6) ~~business signs~~ **logo panels** for "GAS", "FOOD", "LODGING", ~~and~~ "CAMPING", **and "ATTRACTION".**

(b) At double-exit interchanges, the specific ~~information panels~~ **service signs** shall consist of two (2) sections, one (1) for each exit. The top section shall display the ~~business signs~~ **logo panels** for the first exit, and the lower section shall display the ~~business signs~~ **logo panels** for the second exit. The name of the type of service followed by the exit number shall be displayed in a line above the ~~business signs~~ **logo panels** in each section. At unnumbered interchanges, the legend "NEXT RIGHT (LEFT)" and "SECOND RIGHT (LEFT)" shall be substituted for the exit numbers. Where a type of motorist service is to be signed for at only one (1) exit, one (1) section of the specific ~~information panel~~ **service sign** may be omitted, or a single-exit interchange sign may be used. The number of ~~business signs~~ **logo panels** on the **specific service** sign ~~panel~~ (total of both sections) shall be limited to six (6) for "GAS", "FOOD", "LODGING", ~~and~~ "CAMPING", **and "ATTRACTION".**

(c) At remote rural interchanges, where ~~not more than two (2)~~ **the number of** qualified **business** facilities are ~~available for each of two (2) or more types of services, business signs~~ **limited, or at interchanges where longitudinal space limits the number of specific service signs that may be installed, logo panels** for **two (2) or** three (3) types of services may be displayed on the same **specific service** sign. ~~panel. Not more than three (3) business signs for each type of service shall be displayed in combination on a panel.~~ **The permitted combinations are:**

(1) Up to two (2) logo panels for up to three (3) types of services.

(2) Up to three (3) logo panels for two (2) types of services.

(3) Up to four (4) logo panels for one (1) type of service and up to two (2) logo panels for one (1) other type of service.

The name of each type of service shall be displayed above its respective ~~business sign(s),~~ **logo panel(s),** and the exit number shall be displayed above the names of the types of services. At unnumbered interchanges, the legend "NEXT RIGHT (LEFT)" shall be substituted for the exit number. ~~Business signs~~ **Logo panels** should not be combined on a ~~panel~~ **specific service sign** when it is anticipated that additional service facilities will become available in the near future. When it becomes necessary to display ~~a fourth business sign~~ **more logo panels** for a type of service displayed in combination, the ~~business signs~~ **logo panels** involved shall then be displayed in compliance with subsection *[subsections]* (a) through (b).

(d) The normal orientation for specific service signs is with the longer dimension horizontal. At locations with extreme conditions, such as narrow right-of-way or steep slopes, where a horizontal installation is not practical, the longer dimension may be installed vertical with sections appropriate to the vertical orientation. The left section shall be for the first exit of a double-exit interchange and the right section for the second exit.

(e) When a specific service sign is divided into sections, a section may not be extended left or right, up or down to encroach into the area of another section. Specific service signs not in compliance with this provision *[this section]* **at the time this rule is adopted may remain in place until the earlier of:**

(1) the end of the normal service life of the sign; or

(2) a logo panel in the section with the extension is removed so that sections that comply may be established.

(Indiana Department of Transportation; 105 IAC 9-4-11; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2328; filed Mar 2, 1988, 10:55 a.m.: 11 IR 2332; filed Mar 30, 1990, 3:30 p.m.: 13 IR 1390; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2441) NOTE: Transferred from Department of Highways (120 IAC 4-5-11) to Indiana Department of Transportation (105 IAC 9-4-11) by P.L.112-1989, SECTION 5, effective July 1, 1989.

SECTION 9. 105 IAC 9-4-12 IS AMENDED TO READ AS FOLLOWS:

105 IAC 9-4-12 Size; special requirements

Authority: IC 8-23-2-6
Affected: IC 9-21-4

Sec. 12. (a) Each ~~business sign~~ **logo panel** displayed on the "GAS" specific ~~information panel~~ **service sign** shall be contained within a forty-eight (48) inch wide and thirty-six (36) inch high rectangular background area, including border.

(b) Each ~~business sign~~ **logo panel** on the "FOOD", "LODGING", ~~and~~ "CAMPING", **and "ATTRACTION"** specific ~~information panels~~ **service signs** shall be contained within a sixty (60) inch wide and thirty-six (36) inch high rectangular background area, including border.

(c) All letters used in the name of the type of service and the directional legend shall be ten (10) inch capital letters. Numbers shall be ten (10) inches in height. *(Indiana Department of Transportation; 105 IAC 9-4-12; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2329; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2442) NOTE: Transferred from Department of Highways (120 IAC 4-5-12) to Indiana Department of Transportation (105 IAC 9-4-12) by P.L.112-1989, SECTION 5, effective July 1, 1989.*

SECTION 10. 105 IAC 9-4-13 IS AMENDED TO READ AS FOLLOWS:

105 IAC 9-4-13 Qualification for logo panels

Authority: IC 8-23-2-6
Affected: IC 9-21-4

Sec. 13. (a) In addition to the specific requirements in this section, each applicant must hold valid licenses, permits, and/or approvals required of the facility by any appropriate governmental agency. **Each business identified on a specific service sign must give written assurance to the state, or the contractor, of its conforming with all applicable laws concerning the provisions of public accommodations without regard to race, religion, color, sex, disability, or ancestry, and must not be in breach of that assurance.**

(b) To qualify as ~~a primary~~ **an** applicant for a "GAS" ~~business sign,~~ **logo panel,** a business **facility** must establish the following:

(1) Provide vehicle services, including fuel, oil, ~~tire repair,~~ and water. ~~It is permissible for a subcontractor to provide tire repair service on the premises of the primary applicant.~~ **Tire repair must be provided on-site, or information about tire repair off-site must be conspicuously posted. Tire repair shall be:**

(A) sixteen (16) hours a day for seven (7) days a week for a primary applicant; or

(B) twelve (12) hours a day for seven (7) days a week for a secondary applicant; and

(C) performed on-site by employees or a subcontractor within one (1) hour; or

(D) performed off-site within a reasonable driving distance by another provider, with a list of off-site tire repair providers and copies of written directions to the provider available to motorists at the applicant's establishment.

(2) Provide **modern** public restroom facilities and drinking water.

(3) Be in continuous operation with a minimum of:

(A) Sixteen (16) hours a day for seven (7) days a week **for a primary applicant.**

(B) Twelve (12) hours a day for seven (7) days a week for a secondary applicant.

(4) Provide a public telephone.

(5) Be located within two (2) miles of the interchange and be on, or readily visible from, the intersecting crossroad.

(c) To qualify as ~~a primary~~ **an** applicant for a "FOOD" ~~business sign,~~ **logo panel,** a business **facility** must establish the following:

~~(1) Open on or before 8:30 a.m.~~

~~(2) Provide twelve (12) hours of service a day and serve three (3) meals a day, seven (7) days a week, with a minimum seating capacity of twenty-five (25) persons.~~

~~(3)~~ **(1)** Provide **modern** public restroom facilities.

~~(4)~~ **(2)** Provide a public telephone.

~~(5)~~ **(3)** Be located within three (3) miles of the interchange and be on, or readily visible from, the intersecting crossroad.

(4) Provide a minimum seating capacity of twenty-five (25) persons.

(5) Provide meals a minimum of six (6) days per week. If applicable, the day of the week the business facility is not in operation shall be shown on or below the logo panel.

(6) Provide meal services a minimum of:

(A) Twelve (12) hours operation for three (3) meals a day opening at or before 8:30 a.m. for a primary applicant.

(B) Two (2) meals per day for secondary applicant.

(d) To qualify as ~~a primary~~ **an** applicant for a "LODGING" ~~business sign,~~ **logo panel,** a business must establish the following:

(1) Provide a minimum of ten (10) separate sleeping units **with modern sanitary facilities.**
(2) Provide a public telephone.
(3) Have gasoline and food available within one (1) mile of the facility, between the facility and the interchange, or within the respective limits stipulated in subsections (b) and (c).
(4) Be located within three (3) miles of the interchange and be on, or readily visible from, the intersecting crossroad.

(e) To qualify as ~~a primary~~ **an** applicant for a "CAMPING" ~~business sign,~~ **logo panel,** a business **facility** must establish the following:
(1) Provide adequate waste disposal.
(2) Provide **modern sanitary facilities, including** an adequate number of toilets, ~~and~~ lavatories, **and showers** for ~~camper parking~~ **camping sites'** capacity.
(3) Provide running water, ~~with showers~~ **drinking water,** and electricity.
(4) Provide a minimum ~~of fifty (50) overnight camper~~ **number of camping** sites:
(A) Fifty (50) for primary applicant.
(B) Twenty-five (25) for secondary applicant.
(5) Be located within fifteen (15) miles of the interchange.
(6) Provide a public telephone.
(7) Provide ~~twelve (12) month~~ **continuous months of** operation: ~~or provide for "Closed" panels overlaying the business sign during the seasonal closing. The closed panel will be fabricated and erected at the applicant's expense. Posting of the closed panel, and subsequent removal, will be limited to a one (1) time per year basis.~~
(A) Twelve (12) months for primary applicant.
(B) Six (6) months for secondary applicant. The secondary applicant shall provide for "CLOSED" panels during the months of closure. Posting of the closed panel, and subsequent removal, will be limited to one (1) time per year. Alternatively, the months of operation may be posted on or below the logo panel.
(8) Provide adequate trailblazing from the interchange to the facility.

(f) To qualify as ~~a secondary~~ **an** applicant for ~~a "GAS" business sign,~~ **an "ATTRACTION" logo panel,** a business must establish the following:
~~(1) Provide vehicle services including fuel, oil, tire repair, and water. It is permissible for a subcontractor to provide tire repair service on the premises of the secondary applicant.~~
(1) Be of regional significance.
(2) Have adequate off-street parking for normal visitor demand.
~~(2)~~ **(3)** Provide **modern** public restroom facilities and drinking water.
~~(3) Be in continuous operation for a minimum of twelve (12) hours a day for seven (7) days a week.~~
(4) Provide a public telephone.
(5) Be located within ~~two (2)~~ **fifteen (15)** miles of the interchange. ~~and be on, or readily visible from, the intersecting crossroad.~~
(6) Provide adequate trailblazing from the interchange to the facility.
(7) Be one (1) or more of the following:
(A) Amusement park. A commercially operated park enterprise which supplies refreshments and various forms and devices for entertainment.
(B) Business district/main street community. The central business district of a community or an area within a community which has been officially designated as a main street comnnunity *[sic., community]* **by the Indiana department of commerce. To qualify for this type of signage at an exit, there must be more than one (1) exit from the highway to access the community.**
(C) Education center. A facility which is of outstanding educational value and which conducts tours on a regularly scheduled basis throughout the year.
(D) Golf course. Eighteen (18) hole minimum United States Golf Association regulation governed. Secondary applicant is the only applicant status available for golf course regardless of operation times outlined in *[subdivision]* **(8) below.**
(E) Historical site. A structure, district, or site listed on the Indiana Register of Historic Sites and Structures or the National Register of Historic Places as being of historical significance and which is open to the public.
(F) Museum. An organized and permanent institution, with professional staff, essentially educational or aesthetic in purpose, which owns or utilizes tangible objects, cares for them, and exhibits them to the public on some regular schedule.
(G) Religious site. A shrine, grotto, or similar type site which is of a unique religious nature.
(H) Resort/ski area/marina. A facility with those recreational amenities normally present at a facility which is the main focal point of a vacation and which is situated to take advantage of a natural, historic, or recreational attraction.
(I) U-pick/orchard/farmer's market. An established area or facility where consumers can purchase consumer picked or prepicked fresh Indiana grown food directly from Indiana producers.
(J) Winery. A facility that produces wine from grapes or other fruit and maintains a tasting room, sales, and tours.
(K) Botanical/zoological facility. A facility that houses and maintains a collection of unique living animals or plants and is open to the public.
(8) Have regularly scheduled operation for a minimum of:
(A) Eight (8) hours per day, seven (7) days per week all year for primary applicant.
(B) Six (6) hours per day for five (5) days per week for eight (8) continuous months per year for secondary applicant. If applicable, the day(s) of the week the

business facility is not in operation shall be shown on or below the logo panel. The secondary applicant shall provide for "CLOSED" panels during the months of closure. Posting of the closed panel, and subsequent removal, will be limited to one (1) time per year. Alternatively, the months of operation may be posted on or below the logo panel.

~~(g) To qualify as a secondary applicant for a "FOOD" business sign, a business must establish the following:~~

~~(1) Serve two (2) meals a day, seven (7) days a week, with a minimum seating capacity of twenty-five (25) persons.~~

~~(2) Provide public restroom facilities.~~

~~(3) Provide a public telephone.~~

~~(4) Be located within three (3) miles of the interchange and be on, or readily visible from, the intersecting crossroad.~~

~~(h)~~ **(g)** The department or its contractor will enter into contracts with primary applicants for the use of space on specific ~~information panels.~~ **service signs.** If space remains available on ~~"GAS" and "FOOD" information panels~~ **specific service signs** after primary applicants have been ~~contacted,~~ **contracted,** the department or its contractor may enter into contracts with secondary applicants for use of the remaining space. *(Indiana Department of Transportation; 105 IAC 9-4-13; filed Aug 13, 1984, 2:54 p.m.: 7 IR 2329; errata, 7 IR 2546; filed Mar 2, 1988, 10:55 a.m.: 11 IR 2333; filed Oct 5, 1993, 5:00 p.m.: 17 IR 173; readopted filed Nov 7, 2001, 3:20 p.m.: 25 IR 899; filed Mar 21, 2002, 4:40 p.m.: 25 IR 2442) NOTE: Transferred from Department of Highways (120 IAC 4-5-13) to Indiana Department of Transportation (105 IAC 9-4-13) by P.L.112-1989, SECTION 5, effective July 1, 1989.*

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TITLE 355 STATE CHEMIST OF THE STATE OF INDIANA

LSA Document #01-335(F)

DIGEST

Adds 355 IAC 6 to provide detailed labeling requirements consistent with nutritional parameters necessary for livestock and pet foods. Effective 30 days after filing with the secretary of state.

355 IAC 6

SECTION 1. 355 IAC 6 IS ADDED TO READ AS FOLLOWS:

ARTICLE 6. ANIMAL FOODS

Rule 1. General Provisions

355 IAC 6-1-1 Definitions and terms
Authority: IC 15-5-13-14
Affected: IC 15-5-13-1; IC 15-5-13-9

Sec. 1. (a) The names and definitions for commercial feeds shall be the official definitions of feed ingredients adopted by the Association of American Feed Control Officials (AAFCO), except as the director designates otherwise in specific cases.

(b) The terms used in reference to commercial feeds shall be the official feed terms adopted by the AAFCO, except as the director designates otherwise in specific cases.

(c) The following commodities, when unground and when not mixed or intermixed with other materials, are hereby declared exempt from the definition of commercial feeds under IC 15-5-13-1:
(1) Raw meat.
(2) Hay.
(3) Straw.
(4) Stover.
(5) Silages.
(6) Cobs.
(7) Husks.
(8) Hulls.
Provided that these commodities are not adulterated within the meaning of IC 15-5-13-9.

(d) The individual chemical compounds and substances of loose salt (sodium chloride) are hereby declared exempt from the definition of commercial feed under IC 15-5-13-1.

(e) Unmanipulated high moisture (greater than ninety percent (90%) moisture) human food processing byproducts are hereby declared exempt from the definition of commercial feed under IC 15-5-13-1 provided they are not adulterated within the meaning of IC 15-5-13-9.

(f) "Custom-mixed feed" includes feed to which the manufacturer retains title and which is fed to animals to which the manufacturer retains title. *(State Chemist of the State of Indiana; 355 IAC 6-1-1; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2444)*

355 IAC 6-1-2 Label format
Authority: IC 15-5-13-14
Affected: IC 15-5-13

Sec. 2. (a) Commercial feed, other than custom-mixed feed, shall be labeled with the information prescribed in this rule on the principal display panel of the product and in the following format:

(1) Product name and brand name, if any, as stipulated in section 3(a)(1) of this rule.

(2) If a drug is used, label as stipulated in section 3(a)(2) of this rule.

(3) Purpose statement as stipulated in section 3(a)(3) of this rule.

(4) Guaranteed analysis as stipulated in section 3(a)(4) of this rule.

(5) Feed ingredients as stipulated in section 3(a)(5) of this rule.

(6) Directions for use and precautionary statements as stipulated in section 3(a)(6) of this rule.

(7) Name and principal mailing address of the manufacturer or person responsible for distributing the feed as stipulated in section 3(a)(7) of this rule.

(8) Quantity statement.

(b) The following requirements apply to labeling:

(1) The information required in subsection (a)(1) through (a)(5), (a)(7), and (a)(8) must appear in its entirety on one (1) side of the label or on one (1) side of the container.

(2) The information required by subsection (a)(6) shall be displayed in a prominent place on the label or container but not necessarily on the same side as the information in subdivision (1). When the information required by subsection (a)(6) is placed on a different side of the label or container, it shall be referenced on the front side with a statement, such as "See back of label for directions for use.". None of the information required by this section shall be subordinated or obscured by other statements or designs.

(c) Custom mixed feed shall be accompanied with the information prescribed in this rule using labels, invoice, delivery ticket, or another distribution document bearing the following information:

(1) The name and address of the manufacturer.

(2) The name and address of the purchaser.

(3) The date of sale or delivery.

(4) The custom mixed feed name and brand name if any.

(5) The product name and net quantity of each commercial feed and each other ingredient used in the mixture.

(6) The direction for use and precautionary statements as required by sections 7 and 8 of this rule.

(7) If a drug containing product is used, the:

(A) purpose of the medication (claim statement); and

(B) established name of each active drug ingredient and the level of each drug used in the final mixture expressed in accordance with section 4(d) of this rule.

(State Chemist of the State of Indiana; 355 IAC 6-1-2; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2444)

355 IAC 6-1-3 Label information

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6; IC 15-5-13-8

Sec. 3. (a) Commercial feed, other than custom-mixed feed, shall be labeled with the information prescribed as follows:

(1) Product name and brand name, if any, as follows:

(A) The brand or product name must be appropriate for the intended use of the feed and must not be misleading. If the name indicates the feed is made for a specific use, the character of the feed must conform therewith. A commercial feed for a particular animal class must be suitable for that purpose.

(B) Commercial, registered brand or trade names are not permitted in guarantees or ingredient listings and only in the product name of feeds produced by or for the firm holding the rights to such a name.

(C) The name of a commercial feed shall not be derived from one (1) or more ingredients of a mixture to the exclusion of other ingredients and shall not be one representing any components of a mixture unless all components are included in the name, provided, that if any ingredient or combination of ingredients is intended to impart a distinctive characteristic to the product which is of significance to the purchaser, the name of that ingredient or combination of ingredients may be used as a part of the brand name or product name if the ingredient or combination of ingredients is quantitatively guaranteed in the guaranteed analysis, and the brand or product name is not otherwise false or misleading.

(D) The word "protein" shall not be permitted in the product name of a feed that contains added nonprotein nitrogen.

(E) When the name carries a percentage value, it shall be understood to signify protein and/or equivalent protein from nonprotein nitrogen content only, even though it may not explicitly modify the percentage with the word "protein", provided that other percentage values may be permitted if they are followed by the proper description and conform to good labeling practices. Digital numbers shall not be used in a product name in such a manner as to be misleading or confusing to the customer.

(F) Single ingredient feeds shall have a product name in accordance with the designated definition of feed ingredients as recognized by the Association of American Feed Control Officials unless the director designates otherwise.

(G) The word "vitamin", or a contraction thereof, or any word suggesting vitamin can be used only in the name of a feed which is represented to be a vitamin supplement, and which is labeled with the minimum content of each vitamin declared, as specified in section 4(c) of this rule.

(H) The term "mineralized" shall not be used in the

name of a feed except for "TRACE MINERALIZED SALT". When so used, the product must contain significant amounts of trace minerals which are recognized as essential for animal nutrition.

(I) The term "meat" and "meat byproducts" shall be qualified to designate the animal from which the meat and meat byproducts is derived unless the meat and meat byproducts are made from cattle, swine, sheep, and goats.

(2) If a drug is used, the following requirements apply:

(A) The word "medicated" shall appear directly following and below the product name in type size, no smaller than half the type size of the product name.

(B) Purpose statement as required in subdivision (3).

(C) The purpose of medication (claim statement).

(D) An active ingredient statement listing the active drug ingredients by their established name and the amounts in accordance with section 4(d) of this rule.

(3) Requirements for purpose statement are as follows:

(A) The statement of purpose shall contain the specific species and animal class or classes for which the feed is intended as defined in subdivision (4).

(B) The manufacturer shall have flexibility in describing in more specific and common language the defined animal class, species, and purpose while being consistent with the category of animal class defined in subdivision (4), which may include, but is not limited to, weight range, sex, or age of the animal for which the feed is manufactured.

(C) The purpose statement may be excluded from the label if the product name includes a description of the species and animal class or classes for which the product is intended.

(D) The purpose statement of a premix for the manufacture of feed may exclude the animal class and species and state "For Further Manufacture of Feed" if the nutrients contained in the premix are guaranteed and sufficient for formulation into various animal species feeds and premix specifications are provided by the end user of the premix. This section is applicable to commercial feeds regulated under subdivision (4)(J)(ii)(JJ).

(E) The purpose statement of a single purpose ingredient blend, such as a blend of animal protein products, milk products, fat products, roughage products, or molasses products may exclude the animal class and species and state "For Further Manufacture of Feed" if the label guarantees of the nutrients contained in the single purpose nutrient blend are sufficient to provide for formulation into various animal species feeds. This section is applicable to commercial feeds regulated under subdivision (4)(J)(ii)(JJ).

(F) The purpose statement of a product shall include a statement of enzyme functionality if enzymatic activity is represented in any manner.

(4) Guarantees for crude protein, equivalent crude protein from nonprotein nitrogen, amino acids, crude fat, crude fiber, acid detergent fiber, calcium, phosphorus, salt, and sodium shall be the sequence of nutritional guarantees when such guarantee is stated. Other required and voluntary guarantees should follow in a general format such that the units of measure used to express guarantees (percentage, parts per million, International Units, etc.) are listed in a sequence that provides a consistent grouping of the units of measure as follows:

(A) Required guarantees for swine formula feeds are as follows:

(i) Animal classes as follows:

(AA) Prestarter, two (2) to eleven (11) pounds.

(BB) Starter, eleven (11) to forty-four (44) pounds.

(CC) Grower, forty-four (44) to one hundred ten (110) pounds.

(DD) Finisher, one hundred ten (110) to two hundred forty-two (242) pounds (market).

(EE) Gilts, sows, and adult boars.

(FF) Lactating gilts and sows.

(ii) Guaranteed analysis for swine complete feeds and supplements (all animal classes) as follows:

(AA) Minimum percentage of crude protein.

(BB) Minimum percentage of lysine.

(CC) Minimum percentage of crude fat.

(DD) Maximum percentage of crude fiber.

(EE) Minimum and maximum percentage of calcium.

(FF) Minimum percentage of phosphorus.

(GG) Minimum and maximum percentage of salt (if added).

(HH) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(II) Minimum selenium in parts per million.

(JJ) Minimum zinc in parts per million.

(B) Required guarantees for formula poultry feeds (broilers, layers, and turkeys) as follows:

(i) Animal classes as follows:

(AA) Layer, chickens that are grown to produce eggs for food, for example, table eggs:

(aa) starting/growing, from day of hatch to approximately ten (10) weeks of age;

(bb) finisher, from approximately ten (10) weeks of age to the time first egg is produced (approximately twenty (20) weeks of age);

(cc) laying, from the time the first egg is laid throughout the time of egg production; and

(dd) breeders, chickens that produce fertile eggs for hatch replacement layers to produce eggs for food, table eggs, from the time the first egg is laid throughout their productive cycle.

(BB) Broilers, chickens that are grown for human food:

(aa) starting/growing, from the day of hatch to approximately five (5) weeks of age;

(bb) finisher, from approximately five (5) weeks

of age to market, (forty-two (42) to fifty-two (52) days); and

(cc) breeders, hybrid strains of chickens whose offspring are grown for human food (broilers) any age and either sex.

(CC) Broilers, breeders, chickens whose offspring are grown for human food (broilers):

(aa) starting/growing, from the day of hatch until approximately ten (10) weeks of age;

(bb) finishing, from approximately ten (10) weeks of age to the time the first egg is produced, approximately twenty (20) weeks of age; and

(cc) laying, fertile egg producing chickens (broilers/roasters) from the day of the first egg throughout the time fertile eggs are produced.

(DD) Turkeys:

(aa) starting/growing, turkeys that are grown for human food from the day of the hatch to approximately thirteen (13) weeks of age (females) and sixteen (16) weeks of age (males);

(bb) finisher, turkeys that are grown for human food, females from approximately thirteen (13) weeks of age to approximately seventeen (17) weeks of age; males from sixteen (16) weeks of age to twenty (20) weeks of age (or desired market weight);

(cc) laying, female turkeys that are producing eggs; from the time the first egg is produced, throughout the time they are producing eggs; and

(dd) breeder, turkeys that are grown to produce fertile eggs, from the day of hatch to the time the first eggs produced (approximately thirty (30) weeks of age), both sexes.

(ii) Guaranteed analysis for poultry complete feeds and supplements (all animal classes):

(AA) minimum percentage of crude protein;

(BB) minimum percentage of lysine;

(CC) minimum percentage of methionine;

(DD) minimum percentage of crude fat;

(EE) maximum percentage of crude fiber;

(FF) minimum and maximum percentage of calcium;

(GG) minimum percentage of phosphorus;

(HH) minimum and maximum percentage of salt (if added); and

(II) minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(C) Required guaranteed for beef cattle formula feeds as follows:

(i) Animal classes as follows:

(AA) Calves (birth to weaning).

(BB) Cattle on pasture may be specific as to production stage, for example:

(aa) stocker;

(bb) feeder;

(cc) replacement heifers;

(dd) brood cows; or

(ee) bulls.

(CC) Feedlot cattle.

(ii) Guaranteed analysis for beef complete feeds and supplements (all animal classes) as follows:

(AA) Minimum percentage of crude protein.

(BB) Maximum percentage of equivalent crude protein from nonprotein nitrogen when added.

(CC) Minimum percentage of crude fat.

(DD) Maximum percentage of crude fiber.

(EE) Minimum and maximum percentage of calcium.

(FF) Minimum percentage of phosphorus.

(GG) Minimum and maximum percentage of salt (if added).

(HH) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(II) Minimum percentage of potassium.

(JJ) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).

(iii) Guaranteed analysis for beef mineral feeds (if added) as follows:

(AA) Minimum and maximum percentage calcium.

(BB) Minimum percentage of phosphorus.

(CC) Minimum and maximum percentage of salt.

(DD) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(EE) Minimum percentage of magnesium.

(FF) Minimum percentage of potassium.

(GG) Minimum copper in parts per million.

(HH) Minimum selenium in parts per million.

(II) Minimum zinc in parts per million.

(JJ) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound.

(D) Required guarantees for dairy formula feeds as follows:

(i) Animal classes as follows:

(AA) Veal milk replacer, milk replacer to be fed for veal production.

(BB) Herd milk replacer, milk replacer to be fed for herd replacement calves.

(CC) Starter, approximately three (3) days to three (3) months.

(DD) Growing heifers, bulls, and dairy beef as follows:

(aa) Grower 1, three (3) months to twelve (12) months of age.

(bb) Grower 2, more than twelve (12) months of age.

(EE) Lactating dairy cattle.

(FF) Nonlactating dairy cattle.

(ii) Guaranteed analysis for veal and herd replacement milk replacer as follows:

(AA) Minimum percentage crude protein.

(BB) Minimum percentage crude fat.

(CC) Maximum percentage of crude fiber.

(DD) Minimum and maximum percentage calcium.

(EE) Minimum percentage of phosphorus.

(FF) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).

(iii) Guaranteed analysis for dairy cattle complete feeds and supplements as follows:

(AA) Minimum percentage of crude protein.

(BB) Maximum percentage of equivalent crude protein from nonprotein nitrogen when added.

(CC) Minimum percentage of crude fat.

(DD) Maximum percentage of crude fiber.

(EE) Maximum percentage of acid detergent fiber.

(FF) Minimum and maximum percentage of calcium.

(GG) Minimum percentage of phosphorus.

(HH) Minimum selenium in parts per million.

(II) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).

(iv) Required guaranteed analysis for dairy mixing and pasture mineral as follows:

(AA) Minimum and maximum percentage of calcium.

(BB) Minimum percentage of phosphorus.

(CC) Minimum and maximum percentage of salt.

(DD) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(EE) Minimum percentage of magnesium.

(FF) Minimum percentage of potassium.

(GG) Minimum selenium in parts per million.

(HH) Minimum vitamin A, other than the precursors of vitamin A, in International Units per pound.

(E) Required guarantees for equine formula feeds as follows:

(i) Animal classes as follows:

(AA) Foal.

(BB) Mare.

(CC) Breeding.

(DD) Maintenance.

(ii) Guaranteed analysis for equine complete feeds and supplements (all animal classes) as follows:

(AA) Minimum percentage of crude protein.

(BB) Minimum percentage of crude fat.

(CC) Maximum percentage of crude fiber.

(DD) Minimum and maximum percentage of calcium.

(EE) Minimum percentage of phosphorus.

(FF) Minimum copper in parts per million.

(GG) Minimum selenium in parts per million.

(HH) Minimum zinc in parts per million.

(II) Minimum vitamin A, other than the precursors of vitamin A, in International Units per pound (if added).

(iii) Guaranteed analysis for equine mineral feeds (all animal classes) as follows:

(AA) Minimum and maximum percentage of calcium.

(BB) Minimum percentage of phosphorus.

(CC) Minimum and maximum percentage of salt (if added).

(DD) Minimum and maximum percentage of sodium shall be guaranteed only when the total sodium exceeds that furnished by the maximum salt guarantee.

(EE) Minimum copper in parts per million.

(FF) Minimum selenium in parts per million.

(GG) Minimum zinc in parts per million.

(HH) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).

(F) Required guaranteed for goat and sheep formula feeds as follows:

(i) Animal classes as follows:

(AA) Starter.

(BB) Grower.

(CC) Finisher.

(DD) Breeder.

(EE) Lactating.

(ii) Guaranteed analysis for goat and sheep complete feeds and supplements (all animal classes) as follows:

(AA) Minimum percentage of crude protein.

(BB) Maximum percentage of equivalent crude protein from nonprotein nitrogen when added.

(CC) Minimum percentage of crude fat.

(DD) Maximum percentage of crude fiber.

(EE) Minimum and maximum percentage of calcium.

(FF) Minimum percentage of phosphorus.

(GG) Minimum and maximum percentage of salt (if added).

(HH) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(II) Minimum and maximum copper in parts per million (if added, or if total copper exceeds twenty (20) parts per million).

(JJ) Minimum selenium in parts per million.

(KK) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).

(G) Required guarantees for duck and geese formula feeds as follows:

(i) Animal classes as follows:

(AA) Ducks as follows:

(aa) Starter, zero (0) to three (3) weeks of age.

(bb) Grower, three (3) to six (6) weeks of age.

(cc) Finisher, six (6) weeks to market.

(dd) Breeder developer, eight (8) to nineteen (19) weeks of age.

(ee) Breeder, twenty-two (22) weeks to end of lay.

(BB) Geese as follows:

(aa) Starter, zero (0) to four (4) weeks of age.

(bb) Grower, four (4) to eight (8) weeks of age.

(cc) Finisher, eight (8) weeks to market.

(dd) Breeder developer, ten (10) to twenty-two (22) weeks of age.

(ee) Breeder, twenty-two (22) weeks to end of lay.

(ii) Guaranteed analysis for duck and geese complete feeds and supplements (for all animal classes) as follows:

(AA) Minimum percentage of crude protein.

(BB) Minimum percentage of crude fat.

(CC) Maximum percentage of crude fiber.

(DD) Minimum and maximum percentage of calcium.

(EE) Minimum percentage of phosphorus.

(FF) Minimum and maximum percentage of salt (if added).

(GG) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(H) Required guarantees for fish complete feeds and supplements as follows:

(i) Animal species shall be declared in lieu of animal class as follows:

(AA) Trout.

(BB) Catfish.

(CC) Species other than trout or catfish.

(ii) Guaranteed analysis for all fish complete feeds and supplements as follows:

(AA) Minimum percentage of crude protein.

(BB) Minimum percentage of crude fat.

(CC) Maximum percentage of crude fiber.

(DD) Minimum percentage of phosphorus.

(I) Required guarantees for rabbit complete feeds and supplements as follows:

(i) Animal classes as follows:

(AA) Grower, four (4) to twelve (12) weeks of age.

(BB) Breeder, twelve (12) weeks of age and over.

(ii) Guaranteed analysis for rabbit complete feeds and supplements (all animal classes) as follows:

(AA) Minimum percentage of crude protein.

(BB) Minimum percentage of crude fat.

(CC) Minimum and maximum percentage of crude fiber (the maximum crude fiber shall not exceed the minimum by more than five (5.0) units).

(DD) Minimum and maximum percentage of calcium.

(EE) Minimum percentage of phosphorus.

(FF) Minimum and maximum percentage of salt (if added).

(GG) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(HH) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).

(J) The required guarantees of grain mixtures with or without molasses and feeds other than those described in clauses (A) through (I) shall include the following items, unless exempted in clause (K), in the order listed as follows:

(i) Animal classes and species for which the product is intended.

(ii) Guaranteed analysis as follows:

(AA) Minimum percentage crude protein.

(BB) Maximum or minimum percentage of equivalent crude protein from nonprotein nitrogen as required in section 4(e) of this rule.

(CC) Minimum percentage of crude fat.

(DD) Maximum percentage of crude fiber.

(EE) Minerals in formula feeds, to include in the following order:

(aa) Minimum and maximum percentages of calcium.

(bb) Minimum percentage of phosphorus.

(cc) Minimum and maximum percentage of salt (if added).

(dd) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.

(ee) Other minerals.

(FF) Minerals in feeds ingredients as specified by the official definitions of the Association of American Feed Control Officials.

(GG) Vitamins in such terms as specified in section 4(c) of this rule.

(HH) Total sugars as invert on dried molasses products or products being sold primarily for their sugar content.

(II) Viable lactic acid producing micro-organisms for use in silages in terms specified in section 4(g) of this rule.

(JJ) A commercial feed, for example, vita-

min/mineral premix or base mix, intended to provide a specialized nutritional source for use in the manufacture of other feeds, must state its intended purpose and guarantee those nutrients relevant to such stated purpose.

(K) Exemptions as follows:

(i) A mineral guarantee for feed, excluding those feeds manufactured as complete feeds and for feed supplements intended to be mixed with grain to produce a complete feed for swine, poultry, fish, and veal and herd milk replacers is not required when the feed or feed ingredient:

(AA) is not intended or represented or does not serve as a principal source of that mineral to the animal; or

(BB) is intended for nonfood producing animals and contains less than six and five-tenths percent (6.5%) total mineral.

(ii) Guarantees for vitamins are not required when the commercial feed is neither formulated for nor represented in any manner as a vitamin supplement.

(iii) Guarantees for crude protein, crude fat, and crude fiber are not required when the commercial feed is intended for purposes other than to furnish these substances or they are of minor significance relating to the primary purpose of the product, such as drug premixes, mineral or vitamin supplements, and molasses.

(iv) Guarantees for micro-organisms are not required when the commercial feed is intended for a purpose other than to furnish these substances or they are of minor significance relating to the primary purpose of the product, and no specific label claims are made.

(v) The indication for animal classes and species is not required on single ingredient products if the ingredient is not intended, represented, or defined for a specific animal class or species.

(vi) Mixtures of whole seeds intended to be fed to wild birds may be labeled showing, by weight percentage, the amount of seed by kind, and a weight designated as "other" that includes weed seed, other crop seed, and inert matter contained in the mixture to total one hundred percent (100%), in lieu of supplying guarantees for minimum crude protein, minimum crude fat, and maximum crude fiber. If the feed contains greater than two and five-tenths percent (2.5%) weed seed by weight, the labeling must include the statement, "Note: This feed contains more than two and five-tenths percent (2.5%) weed seed by weight, printed on the label.".

(5) Feed ingredients, collective terms for the grouping of feed ingredients, or appropriate statements as provided under the provisions of Section 6(4) of IC 15-5-13 *[IC 15-5-13-6(4)]* **as follows:**

(A) The name of each ingredient as defined in the Official Publication of the Association of American Feed Control Officials, common or usual name, or one approved by the director.

(B) Collective terms for the grouping of feed ingredients as defined in the Official Definitions of Feed Ingredients published in the Official Publication of the Association of American Feed Control Officials in lieu of the individual ingredients, provided that:

(i) when a collective term for a group of ingredients is used on the label, individual ingredients within that group shall not be listed on the label; and

(ii) the manufacturer shall provide the feed control official, upon request, with a list of individual ingredients, within a defined group, that are or have been used at manufacturing facilities distributing in or into the state.

(6) Directions for use and precautionary statements or reference to their location if the detailed feeding directions and precautionary statements required by sections 7 and 8 of this rule appear elsewhere on the label.

(7) Name and principal mailing address of the manufacturer or person responsible for distributing the feed. The principal mailing address shall include the street address, city, state, and zip code; however, the street address may be omitted if it is shown in the current city directory or telephone directory.

(8) Net weight or quantity statement.

(b) The director or the director's agent may request labels or labeling under the following conditions:

(1) When the license applicant is a new firm and the labeling practices of the applicant have not been observed.

(2) When labels or labeling of a licensee have been found to be in violation.

(3) When analytical problems are noted.

(4) When a consumer complaint has been received.

(State Chemist of the State of Indiana; 355 IAC 6-1-3; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2445)

355 IAC 6-1-4 Expression of guarantees

Authority: IC 15-5-13-14
Affected: IC 15-5-13

Sec. 4. (a) The guarantees for crude protein, equivalent crude protein from nonprotein nitrogen, lysine, methionine, other amino acids, crude fat, crude fiber, and acid detergent fiber shall be in terms of percentage.

(b) Mineral guarantees as follows:

(1) When the calcium, salt, and sodium guarantees are given in the guaranteed analysis, such shall be stated and conform to the following:

(A) When the minimum is below two and five-tenths percent (2.5%), the maximum shall not exceed the minimum by more than five-tenths (0.5) percentage point.

(B) When the minimum is two and five-tenths percent (2.5%) but less than five percent (5.0%), the maximum shall not exceed the minimum by more than one (1) percentage point.

(C) When the minimum is above five percent (5.0%) or greater the maximum shall not exceed the minimum by more than twenty percent (20%) of the minimum and in no case shall the maximum exceed the minimum by more than five (5) percentage points.

(2) When stated, guarantees for minimum and maximum total sodium and salt, minimum potassium, magnesium, sulfur, phosphorus, and maximum fluoride shall be in terms of percentage. Other minimum mineral guarantees shall be stated in parts per million (ppm) when the concentration is less than ten thousand (10,000) ppm and in percentage when the concentration is ten thousand (10,000) ppm (one percent (1%)) or greater.

(3) Products labeled with a quantity statement, for example, tablets, capsules, granules, or liquid, may state mineral guarantees in milligrams per unit, for example, tablets, capsules, granules, or liquids, consistent with the quantity statement and directions for use.

(c) Guarantees for minimum vitamin content of commercial feeds shall be listed in the order specified and stated in milligrams per pound or in units consistent with those employed for the quantity statement unless otherwise specified as follows:

(1) Vitamin A, other than precursors of vitamin A, in International Units per pound.

(2) Vitamin D3, in products offered for poultry feeding, in International Chick Units per pound.

(3) Vitamin D for other uses, International Units per pound.

(4) Vitamin E, in International Units.

(5) Concentrated oils and feed additive premixes containing vitamins A, D, and/or E may, at the option of the distributor be stated in units per gram instead of units per pound.

(6) Vitamin B12, in milligrams or micrograms per pound.

(7) All other vitamin guarantees shall express the vitamin activity in milligrams per pound in terms of the following:

(A) Menadione.

(B) Riboflavin.

(C) D pantothenic acid.

(D) Thiamine.

(E) Niacin.

(F) Vitamin B6.

(G) Folic acid.

(H) Choline.

(I) Biotin.

(J) Inositol.

(K) P-amino benzoic acid.

(L) Ascorbic acid.

(M) Carotene.

(d) Guarantees for drugs shall be stated in terms of percent by weight, except as follows:

(1) Antibiotics, present as less than two thousand (2,000) grams per ton (total) of commercial feed shall be stated in grams per ton of commercial feed.

(2) Antibiotics present at or more than two thousand (2,000) grams per ton (total) of commercial feed, shall be stated in grams per pound of commercial feed.

(3) Labels for commercial feeds containing growth promotion and/or feed efficiency levels of antibiotics, which are to be fed continuously as the sole ration, are not required to make quantitative guarantees, except as specifically noted in the federal Food Additive Regulations for certain antibiotics, wherein, quantitative guarantees are required regardless of the level or purpose of the antibiotic.

(4) The term "milligrams per pound" may be used for drugs or antibiotics in those cases where a dosage is given in milligrams in the feeding direction.

(e) Commercial feeds containing any added nonprotein nitrogen shall be labeled as follows:

(1) The following for ruminants:

(A) Complete feeds, supplements, and concentrates containing added nonprotein nitrogen and containing more than five percent (5%) protein from natural sources shall be guaranteed as crude protein, minimum, ____%. *[sic.]* **(This includes not more than ____%** *[sic.]* **equivalent protein from nonprotein nitrogen.)**

(B) Mixed feed concentrates and supplements containing less than five percent (5%) protein from natural sources shall be guaranteed as follows:

(i) Equivalent crude protein from nonprotein.

(ii) Nitrogen, minimum, ____% *[sic.]***.**

(C) Ingredient sources of nonprotein nitrogen such as urea, diammonium phosphate, ammonium polyphosphate solution, ammoniated rice hulls, or other basic nonprotein nitrogen ingredients defined by the Association of American Feed Control Officials shall be guaranteed as follows:

(i) Nitrogen, minimum, ____% *[sic.]* **equivalent crude.**

(ii) Protein from nonprotein nitrogen, minimum, ____% *[sic.]***.**

(2) The following for nonruminants:

(A) Complete feeds, supplements, and concentrates containing crude protein from all forms of nonprotein nitrogen, added as such, shall be labeled as crude protein, minimum ____% *[sic.]***. (This includes not more than ____%** *[sic.]* **equivalent crude protein that is not nutritionally available to (species of animal for which feed is intended).)**

(B) Premixes, concentrates, or supplements intended for nonruminants containing more than one and

twenty-five hundredths percent (1.25%) equivalent crude protein from all forms of nonprotein nitrogen, added as such, must contain adequate directions for use and a prominent statement, "WARNING: This feed must be used only in accordance with directions furnished on the label.".

(f) Mineral phosphatic materials for feeding purposes shall be labeled with the guarantee for minimum and maximum percentage of calcium (when present), the minimum percentage of phosphorus, and the maximum percentage of fluorine.

(g) Guarantees for microorganisms shall be stated in colony forming units per gram (CFU/g) when directions are for using the product in grams, or in colony forming units per pound (CFU/lb) when directions are for using the product in pounds. A parenthetical statement following the guarantee shall list each species in order of predominance.

(h) Guarantees for enzymes shall be stated in units of enzymatic activity per unit weight or volume, consistent with label directions. The source organism for each type of enzymatic activity shall be specified, such as protease (bacillus subtilis) five and five-tenths (5.5) milligrams amino acids liberated/min./milligram. If two (2) or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided. *(State Chemist of the State of Indiana; 355 IAC 6-1-4; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2450)*

355 IAC 6-1-5 Suitability
Authority: IC 15-5-13-14
Affected: IC 15-5-13

Sec. 5. (a) The nutritional content of a commercial feed, other than a customer-formula feed, shall be as purported or is represented to possess by its labeling. Such animal feed, its labeling, and intended use must be suitable for the intended purpose of the product.

(b) If the director has reasonable cause to believe a feed is not nutritionally suitable, then the director may request the feed manufacturer to either submit an "Affidavit of Suitability" certifying, or by an alternate procedure certify, the nutritional adequacy of the feed. The Affidavit of Suitability or alternate procedure shall be based on valid scientific evidence. The submission of a completed Affidavit of Suitability shall serve as substantiation of the suitability of the feed.

(c) If an Affidavit of Suitability, or alternative procedure acceptable to the director is not submitted by the feed manufacturer or labeler within thirty (30) days of written notification, the director may deem the feed adulterated under section 7(c) of this rule and order the feed removed from the marketplace.

(d) The Affidavit of Suitability shall contain the following information:

(1) The feed company's name.

(2) The feed's product name.

(3) The name and title of the affiant submitting the document.

(4) A statement that the affiant has knowledge of the nutritional content of the feed and based on valid scientific evidence the feed is nutritionally adequate for its intended purpose.

(5) Date of submission.

(6) The signature of the affiant notarized by a certified notary public.

(State Chemist of the State of Indiana; 355 IAC 6-1-5; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2452)

355 IAC 6-1-6 Ingredients
Authority: IC 15-5-13-14
Affected: IC 15-5-13

Sec. 6. (a) The name of each ingredient or collective term for the grouping of ingredients, when required to be listed, shall be the name as defined in the Official Definitions of Feed Ingredients as published in the Official Publication of the Association of American Feed Control Officials, the common or usual name, or one approved by the director.

(b) The name of each ingredient must be shown in letters or type of the same size.

(c) No reference to quality or grade of an ingredient shall appear in the ingredient statement of a feed.

(d) The term "dehydrated" may precede the name of any product that has been artificially dried.

(e) A single ingredient product defined by the Association of American Feed Control Officials is not required to have an ingredient statement.

(f) Tentative definitions for ingredients shall not be used until adopted as official, unless no official definition exists or the ingredient has a common accepted name that requires no definition, that is, sugar.

(g) When the word "iodized" is used in connection with a feed ingredient, the feed ingredient shall contain not less than seven-thousandths percent (0.007%) iodine, uniformly distributed. *(State Chemist of the State of Indiana; 355 IAC 6-1-6; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2452)*

355 IAC 6-1-7 Directions for use and precautionary statements
Authority: IC 15-5-13-14
Affected: IC 15-5-13

Sec. 7. (a) Directions for use and precautionary state-

ments on the labeling of all commercial feeds and custom-mixed feeds containing additives (including drugs, special purpose additives, or nonnutritive additives) shall:

(1) be adequate to enable safe and effective use for the intended purposes by users with no special knowledge of the purpose and use of such articles; and

(2) include, but not limited to, all information prescribed by all applicable regulations under the federal Food, Drug, and Cosmetic Act.

(b) Adequate directions for use and precautionary statements are required for feeds containing nonprotein nitrogen as specified in section 8 of this rule.

(c) Adequate directions for use and precautionary statements necessary for safe and effective use are required on commercial feeds distributed to supply particular dietary needs or for supplementing or fortifying the usual diet or ration with any vitamin, mineral, or other dietary nutrient or compound. *(State Chemist of the State of Indiana; 355 IAC 6-1-7; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2452)*

355 IAC 6-1-8 Nonprotein nitrogen

Authority: IC 15-5-13-14
Affected: IC 15-5-13

Sec. 8. (a) Urea and other nonprotein nitrogen products defined in the official publication of the Association of American Feed Control Officials are acceptable ingredients only in commercial feeds for ruminant animals as a source of equivalent crude protein. If the commercial feed contains more than eight and seventy-five hundredths percent (8.75%) of the equivalent crude protein from all forms of nonprotein nitrogen, added as such, or the equivalent crude protein from all forms of nonprotein nitrogen, added as such, exceeds one-third (a) of the total crude protein, the label shall bear adequate directions for safe use of feeds and a precautionary statement, "CAUTION: USE AS DIRECTED". The directions for use and the caution statement shall be in type of such size so placed on the label that they will be read and understood by ordinary persons under customary conditions of purchase and use.

(b) Nonprotein nitrogen defined in the official publication of the Association of American Feed Control Officials, when so indicated, are acceptable ingredients in commercial feeds distributed as feed for nonruminant animals as a source of nutrients other than equivalent crude protein. The maximum equivalent crude protein from nonprotein nitrogen sources when used in nonruminant rations shall not exceed one and twenty-five hundredths percent (1.25%) of the total daily ration.

(c) On labels such as those for medicated feeds which bear adequate feeding directions and/or warning statements, the presence of added nonprotein nitrogen shall not require a duplication of the feeding directions or the precautionary statements as long as those statements include sufficient information to ensure the safe and effective use of this product due to the presence of nonprotein nitrogen. *(State Chemist of the State of Indiana; 355 IAC 6-1-8; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2453)*

355 IAC 6-1-9 Drug and feed additives

Authority: IC 15-5-13-14
Affected: IC 15-5-13

Sec. 9. (a) A labeler of a commercial feed that contains additives (including drugs, other special purpose additives, or nonnutritive additives) may be required to submit evidence to prove the safety and efficacy of the commercial feed when used according to the directions furnished on the label.

(b) Satisfactory evidence of safety and efficacy of a commercial feed may be any of the following:

(1) When the commercial feed contains such additives, the use of which conforms to the requirements of the applicable regulation in 21 CFR, or are prior sanctioned, informal review sanctioned, or generally recognized as safe for such use.

(2) When the commercial feed is itself a drug as defined in Section 1(7) *[IC 15-5-13-1(7)]* **and is generally recognized as safe and effective for the labeled use or is marketed subject to an application approved by the Food and Drug Administration under 21 U.S.C. 360(b).**

(3) When one (1) of the purposes for feeding a commercial feed is to impart immunity (that is to act through some immunological process) the constituents imparting immunity have been approved for that purpose through the federal Virus, Serum, and Toxins Act of 1913, as amended.

(4) When the commercial feed is a direct fed microbial product, including the following:

(A) The product meets the particular fermentation product definition.

(B) The microbial content statement, as expressed in the labeling, is limited to the statement, "Contains a source of live (viable) naturally occurring micro-organisms.". This statement shall appear on the label.

(C) The source is stated with a corresponding guarantee expressed in accordance with section 4 of this rule.

(5) When the commercial feed is an enzyme product, including the following:

(A) The product meets the particular enzyme definition defined by the Association of American Feed Control Officials.

(B) The enzyme is stated with a corresponding guarantee expressed in accordance with section 4 of this rule.

(State Chemist of the State of Indiana; 355 IAC 6-1-9; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2453)

355 IAC 6-1-10 Adulterants
Authority: IC 15-5-13-14
Affected: IC 15-5-13-9

Sec. 10. (a) For the purpose of Section 9 of the Act *[IC 15-5-13-9]***, "poisonous or deleterious substances" includes, but is not limited to, the following:**

(1) Fluorine and any mineral or mineral mixture that is to be used directly for the feeding of domestic animals and in which the fluorine exceeds the following:

(A) Twenty-hundredths percent (0.20%) for breeding and dairy cattle.

(B) Thirty-hundredths percent (0.30%) for slaughter cattle.

(C) Thirty-hundredths percent (0.30%) for sheep.

(D) Forty-five hundredths percent (0.45%) for swine.

(E) Sixty-hundredths percent (0.60%) for poultry.

(2) Fluorine bearing ingredients when used in such amounts that they raise the fluorine content of the total ration (exclusive of roughage) above the following amounts:

(A) Four-thousandths percent (0.004%) for breeding and dairy cattle.

(B) Nine-thousandths percent (0.009%) for slaughter cattle.

(C) Six-thousandths percent (0.006%) for sheep.

(D) One-hundredth percent (0.01%) for lambs.

(E) Fifteen-thousandths percent (0.015%) for swine.

(F) Three-hundredths percent (0.03%) for poultry.

(3) Fluorine bearing ingredients incorporated in any feed that is fed directly to cattle, sheep, or goats consuming roughage (with or without) limited amounts of grain, that results in a daily fluorine intake in excess of fifty (50) milligrams of fluorine per one hundred (100) pounds of body weight.

(4) Soybean meal, flakes, or pellets or other vegetable meals, flakes, or pellets that have been extracted with trichlorethylene or other chlorinated solvents.

(5) Sulfur dioxide, sulfurous acid, and salts of sulfurous acid when used in or on feeds or feed ingredients that are considered or reported to be a significant source of vitamin B1 (thiamine).

(b) All screenings or byproducts of grains, and seeds containing weed seeds, when used in commercial feed or sold as such to the ultimate consumer, shall be ground fine enough or otherwise treated to destroy the viability of such weed seeds so that the finished product contains no viable prohibited noxious weed seeds, not more than fifty (50) viable restricted noxious weed seeds per pound, and not more than one hundred (100) per pound of other viable weed seeds. *(State Chemist of the State of Indiana; 355 IAC 6-1-10; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2454)*

355 IAC 6-1-11 Good manufacturing practices
Authority: IC 15-5-13-14
Affected: IC 15-5-13-9

Sec. 11. For the purpose of enforcement of IC 15-5-13-9(9), the director adopts the following as current good manufacturing practices:

(1) The regulations prescribing good manufacturing practices for Type B and Type C medicated feeds as published in 21 CFR 225.

(2) The regulations prescribing good manufacturing practices for Type A medicated articles as published in 21 CFR 226.

(State Chemist of the State of Indiana; 355 IAC 6-1-11; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2454; errata filed April 8, 2002, 11:15 a.m.: 25 IR 2521)

355 IAC 6-1-12 Payment of inspection fee; interstate exclusion
Authority: IC 15-5-13-14
Affected: IC 15-5-13-11; IC 15-5-13-12

Sec. 12. Manufacturers and distributors located in Indiana who furnish substantial quantities of commercial feeds to customers in other states may apply to the director for interstate exclusion status. When so designated, the following conditions apply:

(1) Those distributors shall not be charged the inspection fee by the supplier on commercial feeds purchased from any supplier.

(2) Those distributors shall report and pay the inspection fee on all commercial feeds they distribute in Indiana each quarter including feeds they distribute under another distributor's label.

(3) No credit may be claimed on the quarterly report for payment of the inspection fee to another distributor.

(4) A list of parties designated with interstate exclusion status will be maintained and provided by the director.

(State Chemist of the State of Indiana; 355 IAC 6-1-12; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2454)

355 IAC 6-1-13 Indiana commercial feed license
Authority: IC 15-5-13-14
Affected: IC 15-5-13-3.5

Sec. 13. The application for Indiana commercial feed license shall be on forms provided by the director or forms reproduced locally by the applicant that has all the following information and in the following general order:

(1) Name, complete mailing address, and physical location of the applicant.

(2) Telephone number, FAX number, and e-mail addresses, if applicable.

(3) A list of subsidiaries located in Indiana or any out-of-state subsidiaries who distribute directly into Indiana.

(4) A designation whether the applicant manufactures or distributes commercial feeds under their label in or into Indiana.

(5) A designation whether the applicant manufactures or distributes pet foods or specialty pet foods in containers

of ten (10) pounds or less or containers exceeding ten (10) pounds or bulk.

(6) A designation if the manufacturer is located in Indiana and manufactures only custom-mixed feeds.

(7) The printed name and title of the person who is the contact person for the applicant.

(8) The signature of the applicant.

(State Chemist of the State of Indiana; 355 IAC 6-1-13; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2454)

Rule 2. Pet Food

355 IAC 6-2-1 Definitions and terms

Authority: IC 15-5-13-14
Affected: IC 15-5-13-1

Sec. 1. The definitions in IC 15-5-13 shall apply throughout this rule in addition to the following:

(1) "All life stages" means gestation/lactation, growth, and adult maintenance life stages.

(2) "Family" means a group of products, which are nutritionally adequate for any or all life stages based on their nutritional similarity to a lead product, that has been successfully test-fed according to an AAFCO feeding protocol.

(3) "Immediate container" means the unit, can, box, tin, bag, or other receptacle or covering in which a pet food or specialty pet food is displayed for sale to retail purchasers, but does not include containers used as shipping containers.

(4) "Ingredient statement" means a collective and contiguous listing on the label of the ingredients of which the pet food or specialty pet food is composed.

(5) "Principal display panel" means the part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

(State Chemist of the State of Indiana; 355 IAC 6-2-1; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2455)

355 IAC 6-2-2 Label format and labeling

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6; IC 15-5-13-8

Sec. 2. (a) Pet food and specialty pet food shall be labeled with the following information prescribed in this section:

(1) Product name and brand name, if any, on the principal display panel as stipulated in section 3 of this rule.

(2) The species of pet or specialty pet for which the food is intended conspicuously designated on the principal display panel.

(3) Quantity statement, as defined in Section 6(1) of IC 15-5-13 *[IC 15-5-13-6(1)]***, on the principal display panel.**

(4) Guaranteed analysis as stipulated in section 4 of this rule.

(5) Ingredient statement as stipulated in section 5(a) of this rule.

(6) A statement of nutritional adequacy or purpose if required under section 7 of this rule.

(7) Feeding directions if required under section 8 of this rule.

(8) Name and address of the manufacturer or distributor as stipulated in section 11 of this rule.

(b) When a pet food or specialty pet food enclosed in an outer container or wrapper is intended for retail sale, all required label information shall appear on the outer container or wrapper.

(c) A vignette, graphic, or pictorial representation on a pet food or specialty pet food label shall not misrepresent the contents of the package.

(d) The use of the word "proven" in connection with a label claim for a pet food or specialty pet food is not permitted unless the claim is substantiated by scientific or other empirical evidence.

(e) No statement shall appear upon the label or labeling of a pet food or specialty pet food which makes false or misleading comparisons between that product and any other product.

(f) A personal or commercial endorsement is permitted on a pet food or specialty pet food label provided the endorsement is not false or misleading.

(g) A statement on a pet food or specialty pet food label stating "Improved", "New", or similar designation shall be substantiated and limited to six (6) months production.

(h) A statement on a pet food or specialty pet food label stating preference or comparative attribute claims shall be substantiated and limited to one (1) year production, after which the claim shall be removed or resubstantiated. *(State Chemist of the State of Indiana; 355 IAC 6-2-2; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2455)*

355 IAC 6-2-3 Brand and product names

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6; IC 15-5-13-8

Sec. 3. (a) The words "100%", or "All", or words of similar designation shall not be used in the brand or product name of a pet food or specialty pet food if the product contains more than one (1) ingredient, not including water sufficient for processing, decharacterizing agents, or trace amounts of preservatives and condiments.

(b) An ingredient or a combination of ingredients may form a part of the product name of a pet food or specialty pet food as follows:

(1) When the ingredients derived from animals, poultry, or fish constitutes at least ninety-five percent (95%) of the

total weight of the product. Water sufficient for processing may be excluded when calculating the percentage; however, the ingredient shall constitute at least seventy percent (70%) of the total product weight.

(2) When any ingredient constitutes at least twenty-five percent (25%) of the weight of the product, provided the following:

(A) Water sufficient for processing may be excluded when calculating the percentage; however, the ingredients shall constitute at least ten percent (10%) of the total product weight.

(B) A descriptor is used with the ingredient name. This descriptor shall imply other ingredients are included in the product formula. Examples of descriptors include the following:

(i) Dinner.

(ii) Platter.

(iii) Entree.

(iv) Formula.

(v) Recipe.

(C) The descriptor shall be in the same size, style, and color print as the ingredient name.

(3) When a combination of ingredients that are included in the product name in accordance with this subsection meets all of the following:

(A) Each ingredient constitutes at least three percent (3%) of the product weight, excluding water sufficient for processing.

(B) The names of the ingredients appear in the order of their respective predominance by weight in the product.

(C) All such ingredient names appear on the label in the same size, style, and color print.

(c) When the name of any ingredient appears in the product name of a pet food or elsewhere on the product label and includes a descriptor, such as "with" or similar designation, the named ingredients must each constitute at least three percent (3%) of the product weight exclusive of water for processing. If the names of more than one (1) ingredient are shown, they shall appear in their respective order of predominance by weight in the product. The three percent (3%) minimum level shall not apply to claims for nutrients, such as, but not limited to, vitamins, minerals, and fatty acids, as well as condiments. The word "with," or similar designation, and named ingredients shall be in the same size, style, color, and case print and be of no greater size than:

Panel Size	Max "with claim" Type Size
< 5 sq. in.	c"
5–25 sq. in.	¼"
25–100 sq. in.	d"
100–400 sq. in.	½"
400 sq. in. +	1"

(d) A flavor designation may be included as part of the product name or elsewhere on the label of a pet food or specialty pet food when the flavor designation meets all of the following:

(1) The flavor designation:

(A) conforms to the name of the ingredient as listed in the ingredient statement; or

(B) is identified by the source of the flavor in the ingredient statement.

(2) The word "flavor" is printed in the same size type and with an equal degree of conspicuousness as the name of the flavor designation.

(3) Substantiation of the flavor designation, the flavor claim, or the ingredient source is provided upon request.

(e) The product name of the pet food or specialty pet food shall not be derived from one (1) or more ingredients unless all ingredients are included in the name, except as specified by subsection (b) or (c), provided that the name of an ingredient or combination of ingredients may be used as a part of the product name if:

(1) the ingredient or combination of ingredients is present in sufficient quantity to impart a distinctive characteristic to the product or is present in amounts that have a material bearing upon the price of the product or upon acceptance of the product by the purchaser thereof; or

(2) it does not constitute a representation that the ingredient or combination of ingredients is present to the exclusion of other ingredients.

(f) Contractions or coined names referring to ingredients shall not be used in the brand name of a pet food or specialty pet food unless it is in compliance with subsection (b), (c), or (d). *(State Chemist of the State of Indiana; 355 IAC 6-2-3; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2455)*

355 IAC 6-2-4 Expression of guarantees

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6; IC 15-5-13-8

Sec. 4. (a) The guaranteed analysis shall be listed in the following order and format unless otherwise specified in this rule:

(1) A pet food or specialty pet food label shall list the following required guarantees:

(A) Minimum percentage of crude protein.

(B) Minimum percentage of crude fat.

(C) Maximum percentage of crude fat, if required by section 10 of this rule.

(D) Maximum percentage of crude fiber.

(E) Maximum percentage of moisture.

(F) Additional guarantees shall follow moisture.

(2) When ash is listed in the guaranteed analysis on a pet food or specialty pet food label, it shall be guaranteed as a maximum percentage and shall immediately follow moisture.

(3) A dog or cat food label shall list other required or voluntary guarantees in the same order and units of the nutrients in the AAFCO dog (or cat) food nutrient profiles. Guarantees for substances not listed in the AAFCO dog (or cat) food nutrient profiles, or not otherwise provided for in this rule, shall immediately follow the listing of the recognized nutrients and shall be accompanied by an asterisk referring to the disclaimer "Not recognized as an essential nutrient by the AAFCO dog (or cat) food nutrient profiles.". The disclaimer shall appear immediately after the last such guarantee in the same size type as the guarantees.

(4) A specialty pet food label shall list other required or voluntary guarantees as required by 355 IAC 6-1-3-4(J) *[355 IAC 6-1-3(a)(4)(J)]***.**

(b) The sliding scale method of expressing a guaranteed analysis on a pet food or specialty pet food label (for example, "Minimum crude protein 15-18%") is prohibited.

(c) The label of a pet food or a specialty pet food that is formulated as and represented to be a mineral supplement shall include minimum guarantees for all minerals from sources declared in the ingredient statement:

(1) established by an AAFCO-recognized nutrient profile, expressed as the element in units specified in the nutrient profile; or

(2) expressed as the element in units specified in 355 IAC 6-1-3-4(b) *[355 IAC 6-1-4(b)]* **when no species-specific nutrient profile has been recognized by AAFCO;**

and provided that mineral guarantees required by subdivisions (1) and (2) may be expressed in milligrams per unit, for example, tablets, capsules, granules, or liquids, consistent with those employed in the quantity statement and directions for use, and a weight equivalent, for example, one (1) fluid ounce equals twenty-eight (28) grams, for liquid products.

(d) The label of a pet food or a specialty pet food that is formulated as and represented to be a vitamin supplement shall include minimum guarantees for all vitamins from sources declared in the ingredient statement:

(1) established by an AAFCO-recognized nutrient profile, expressed in units specified in the nutrient profile; or

(2) expressed in units specified in 355 IAC 6-1-3-4(c) *[355 IAC 6-1-4(c)]* **when no species-specific nutrient profile has been recognized by AAFCO;**

and provided that vitamin guarantees required by this subsection may be expressed in approved units, for example, IU, mg, g, per unit, for example, tablets, capsules, granules, or liquids, consistent with those employed in the quantity statement and directions for use, and a weight equivalent, for example, one (1) fluid ounce equals twenty-eight (28) grams, for liquid products.

(e) When the label of a pet food or specialty pet food includes a comparison of the nutrient content of the food with levels established by an AAFCO-recognized nutrient profile, such as a table of comparison, a percentage, or any other designation referring to an individual nutrient or all of the nutrient levels, the following apply:

(1) The product shall meet the AAFCO-recognized nutrient profile.

(2) The statement of comparison shall be preceded by a statement that the product meets the AAFCO-recognized profile; however, the statement that the product meets the AAFCO-recognized nutrient profile is not required provided that the nutritional adequacy statement as per section 7(a)(1) or 7(b)(2)(A) of this rule appears elsewhere on the product label.

(3) The statement of comparison of the nutrient content shall constitute a guarantee, but need not be repeated in the guaranteed analysis.

(4) The statement of comparison may appear on the label separate and apart from the guaranteed analysis.

(f) The maximum moisture declared on a pet food or specialty pet food label shall not exceed seventy-eight percent (78.00%) or the natural moisture content of the ingredients, whichever is higher. However, pet food and specialty pet food, such as, but not limited to, those consisting principally of stew, gravy, sauce, broth, aspic, juice, or a milk replacer, and that are so labeled, may contain moisture in excess of seventy-eight percent (78.00%).

(g) Guarantees for crude protein, crude fat, and crude fiber are not required when the pet food or specialty pet food is intended for purposes other than to furnish these substances or they are of minor significance relative to the primary purpose of the product, such as a mineral or vitamin supplement.

(h) Guarantees for micro-organisms and enzymes shall be stated in the format as stipulated in 355 IAC 6-1-3-4(g) and (h) *[355 IAC 6-1-4(g) and 355 IAC 6-1-4(h)]***.** *(State Chemist of the State of Indiana; 355 IAC 6-2-4; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2456)*

355 IAC 6-2-5 Ingredients

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6; IC 15-5-13-8

Sec. 5. (a) Each ingredient of a pet food or specialty pet food shall be listed in the ingredient statement as follows:

(1) The names of all ingredients in the ingredient statement shall be shown in letters or type of the same size.

(2) The ingredients shall be listed in descending order by their predominance by weight in nonquantitative terms.

(3) Ingredients shall be listed and identified by the name and definition established by AAFCO.

(4) Any ingredient for which no name and definition have been so established shall be identified by the common or usual name of the ingredient.

(b) The ingredients "meat" or "meat byproducts" shall be qualified to designate the animal from which the meat or meat byproducts are derived unless the meat or meat byproducts are derived from cattle, swine, sheep, goats, or any combination thereof. For example, ingredients derived from horses shall be listed as "horsemeat" or "horsemeat byproducts".

(c) Brand or trade names shall not be used in the ingredient statement.

(d) A reference to the quality, nature, form, or other attribute of an ingredient shall be allowed when the reference meets the following:

(1) The designation is not false or misleading.

(2) The ingredient imparts a distinctive characteristic to the pet food or specialty pet food because it possesses that attribute.

(e) A reference to quality or grade of the ingredient does not appear in the ingredient statement. *(State Chemist of the State of Indiana; 355 IAC 6-2-5; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2457)*

355 IAC 6-2-6 Drugs and pet food additives

Authority: IC 15-5-13-14
Affected: IC 15-5-13-1

Sec. 6. (a) An artificial color may be used in a pet food or specialty pet food only if it has been shown to be harmless to pets or specialty pets. The permanent or provisional listing of an artificial color in the United States Food and Drug regulations as safe for use, together with the conditions, limitations, and tolerances, if any, incorporated therein, shall be deemed to be satisfactory evidence that the color is, when used pursuant to such regulations, harmless to pets or specialty pets.

(b) Evidence may be required to prove the safety and efficacy or utility of a pet food or specialty pet food which contains additives or drugs, when used according to directions furnished on the label. Satisfactory evidence of the safety and efficacy of a pet food or specialty pet food may be established when the pet food or specialty pet food:

(1) contains such additives, the use of which conforms to the requirements of the applicable regulation in 21 CFR, or are "prior sanctioned" or "Generally Recognized as Safe" for such use; or

(2) itself is a drug or contains a drug as defined in IC 15-5-13-1-7 *[IC 15-5-13-1(7)]* **and is "generally recognized as safe and effective" for the labeled use or is marketed subject to an application approved by the Food and Drug Administration under 21 U.S.C. 360(b).**

(c) When a drug is included in a pet food or specialty pet food, the format required by 355 IAC 6-1-3(a)(2) for labeling medicated feeds shall be used. *(State Chemist of the State of Indiana; 355 IAC 6-2-6; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2458; errata filed April 8, 2002, 11:15 a.m.: 25 IR 2521)*

355 IAC 6-2-7 Nutritional adequacy

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6

Sec. 7. (a) The label of a pet food or specialty pet food that is intended for all life stages of the pet or specialty pet may include an unqualified claim, directly or indirectly, such as "complete and balanced", "perfect", "scientific", or "100% nutritious" if at least one (1) of the following apply:

(1) The product meets the nutrient requirements for all life stages established by an AAFCO-recognized nutrient profile.

(2) The product meets the criteria for all life stages as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol.

(3) The product is a member of a product family that is nutritionally similar to a lead product that contains a combination of ingredients that has been fed to a normal animal as the sole source of nourishment in accordance with the testing procedures established by AAFCO for all life stages, provided the following:

(A) The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO.

(B) The family product meets the criteria for all life stages.

(C) Under circumstances of reasonable doubt, the director may require the manufacturer to perform additional testing of the family product in order to substantiate the claim of nutritional adequacy.

(b) The label of a pet food or specialty pet food that is intended for a limited purpose or a specific life stage, but not for all life stages, may include a qualified claim, such as "complete and balanced", "perfect", "scientific", or "100% nutritious" when the product and claim meets all of the following:

(1) The claim is qualified with a statement of the limited purpose or specific life stage for which the product is intended or suitable, for example, "complete and balanced for puppies (or kittens)". The claim and the required qualification shall be juxtaposed on the same label panel and in the same size, style, and color print.

(2) The product meets at least one (1) of the following:

(A) The nutrient requirements for the limited purpose or specific life stage established by an AAFCO-recognized nutrient profile.

(B) The criteria for a limited purpose or a specific life

stage as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol.

(C) The requirements of a product family which is nutritionally similar to a lead product which contains a combination of ingredients that, when fed for such limited purpose, will satisfy the nutrient requirements for such limited purpose and has had its capabilities in this regard demonstrated by adequate testing, and provided the following:

(i) The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO.

(ii) The family product meets the criteria for such limited purpose.

(iii) Under circumstances of reasonable doubt, the director may require the manufacturer to perform additional testing for the family product to substantiate the claim of nutritional adequacy.

(c) Dog and cat food labels shall include a statement of nutritional adequacy or purpose of the product, except when the dog or cat food is clearly and conspicuously identified on the principal display panel as a "snack" or "treat". The statement shall consist of one (1) of the following:

(1) A claim that the dog or cat food meets the requirements of one (1) or more of the recognized categories of nutritional adequacy, gestation/lactation, growth, maintenance, and all life stages. The claim shall be stated verbatim as one (1) of the following:

(A) "(Name of product) is formulated to meet the nutritional levels established by the AAFCO Dog (or Cat) Food Nutrient Profiles for _____." (Blank is to be completed by using the stage or stages of the pet's life, such as gestation/lactation, growth, maintenance, or the words "All Life Stages").

(B) "Animal feeding tests using AAFCO procedures substantiate that (Name of Product) provides complete and balanced nutrition for _____." (Blank is to be completed by using the stage or stages of the pet's life tested, such as gestation/lactation, growth, maintenance, or the words "All Life Stages").

(C) "(Name of Product) provides complete and balanced nutrition for _____ (Blank is to be completed by using the stage or stages of the pet's life, such as gestation, lactation, growth, maintenance, or the words "All Life Stages") and is comparable in nutritional adequacy to a product which has been substantiated using AAFCO feeding tests.".

(2) A nutritional or dietary claim for purposes other than those listed in subsection (a) or (b) if the claim is scientifically substantiated.

(3) The statement, "This product is intended for intermittent or supplemental feeding only", if a product does not meet the requirements of subsection (a) or (b) or any other special nutritional or dietary need and so is suitable only for limited or intermittent or supplementary feeding.

(d) A product intended for use by, or under the supervision or direction of a veterinarian shall make a statement in accordance with subsection (c)(1) or (c)(3).

(e) A signed affidavit attesting that the product meets the requirements of subsection (a) or (b)(2) shall be submitted to the director upon request.

(f) If the nutrient content of a product does not meet those nutrient requirements established by an AAFCO-recognized nutrient profile, or if no requirement has been established by an AAFCO recognized nutritional authority for the life stages of the intended species, the claimed nutritional adequacy or purpose of the product shall be scientifically substantiated.

(g) The following AAFCO-recognized nutritional authority, nutrient profile, and/or animal feeding protocol shall be acceptable as the basis for a claim of nutritional adequacy as an AAFCO-recognized nutrient profile or nutritional authority for:

(1) Dogs, the AAFCO dog food nutrient profiles.

(2) Cats, the AAFCO cat food nutrient profiles.

(3) Specialty pets, the nutrient recommendations approved by the Committee on Animal Nutrition of the National Research Council of the National Academy of Sciences, provided that this nutrient recommendation is recognized only for the specific specialty pet for which the profile is intended.

(4) As an AAFCO-recognized animal feeding protocol, the AAFCO Dog and Cat Food Feeding Protocols.

(State Chemist of the State of Indiana; 355 IAC 6-2-7; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2458)

355 IAC 6-2-8 Feeding directions

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6; IC 15-5-13-8

Sec. 8. (a) Dog or cat food, including snacks or treats, labeled as complete and balanced for any or all life stages, as provided in section 7(c)(1) of this rule, except those pet foods labeled in accordance with section 7(d) of this rule, shall list feeding directions on the product label. These directions shall be consistent with the intended use indicated in the nutritional adequacy statement unless a limited use or more limited life stage designation is declared elsewhere, for example, adult formula. These directions shall be expressed in common terms and shall appear prominently on the label. Feeding directions shall, at a minimum, state, "Feed (weight/unit of product) per (weight only) of dog (or cat).". The frequency of feeding shall also be specified.

(b) When a dog or cat food is intended for use by or under the supervision or direction of a veterinarian, the statement, "Use only as directed by your veterinarian" may be used in lieu of feeding directions.

(c) Specialty pet food, including snacks or treats, labeled as complete and balanced for any or all life stages, as provided in section 7(a) of this rule, shall list feeding directions on the product label. These feeding directions shall be adequate to meet the nutrient requirements of the intended species of specialty pet as recommended by the AAFCO-recognized nutritional authority. These directions shall be expressed in common terms and shall appear prominently on the label. The frequency of feeding shall also be specified. *(State Chemist of the State of Indiana; 355 IAC 6-2-8; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2459)*

355 IAC 6-2-9 Statements of calorie content

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6; IC 15-5-13-8

Sec. 9. (a) Except as required in section 10 of this rule, the label of a dog or cat food may bear a statement of calorie content when the label meets all of the following:

(1) The statement shall be separate and distinct from the "Guaranteed Analysis" and shall appear under the heading "Calorie Content".

(2) The statement shall be measured in terms of metabolizable energy (ME) on an as-fed basis and must be expressed as kilocalories per kilogram (kcal/kg) of product, and may also be expressed as kilocalories per familiar household measure, for example, cans, cups, and pounds.

(3) The calorie content is determined by one (1) of the following methods:

(A) By calculation using the following modified Atwater formula:

$$ME(kcal/kg) = 10[(3.5 \times CP) + (8.5 \times CF) + (3.5 \times NFE)]$$

Where: ME = Metabolizable energy.
CP = % crude protein as-fed.
CF = % crude fat as-fed.
NFE = % nitrogen-free extract (carbohydrate) as-fed.

The percentages of CP and CF are the arithmetic averages from proximate analyses of at least four (4) production batches of the product, and the NFE is calculated as the difference between one hundred (100) and the sum of CP, CF, and the percentages of crude fiber, moisture, and ash (determined in the same manner as CP and CF).

(B) In accordance with a testing procedure established by AAFCO.

(4) An affidavit shall be provided upon request to the director, substantiating that the calorie content was determined by either of the following:

(A) Subdivision (3)(A), in which case the results of all the analyses used in the calculation shall accompany the affidavit.

(B) Subdivision (3)(B), in which case the summary data used in the determination of calorie content shall accompany the affidavit.

(5) The calorie content statement shall appear as one (1) of the following:

(A) The claim on the label or other labeling shall be followed parenthetically by the word "calculated" when the calorie content is determined in accordance with subdivision (3)(A).

(B) The value of calorie content stated on the label that is determined in accordance with subdivision (3)(B) shall not exceed or understate the value determined in accordance with subdivision (3)(A) by more than fifteen percent (15%).

(b) Comparative claims shall not be false, misleading, or given undue emphasis and shall be based on the same methodology for the products compared. *(State Chemist of the State of Indiana; 355 IAC 6-2-9; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2460; errata filed April 8, 2002, 11:15 a.m.: 25 IR 2521)*

355 IAC 6-2-10 Descriptive terms

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6; IC 15-5-13-8

Sec. 10. (a) The following are requirements for calorie terms:

(1) "Light" requirements are as follows:

(A) A dog food product that bears on its label the terms "light", "lite", "low calorie", or words of similar designation shall:

(i) contain no more than three thousand one hundred (3,100) kcal ME/kg for products containing less than twenty percent (20%) moisture, no more than two thousand five hundred (2,500) kcal ME/kg for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than nine hundred (900) kcal ME/kg for products containing sixty-five percent (65%) or more moisture;

(ii) include on the label a calorie content statement:

(AA) in accordance with the format provided in section 9 of this rule; and

(BB) that states no more than three thousand one hundred (3,100) kcal ME/kg for products containing less than twenty percent (20%) moisture, no more than two thousand five hundred (2,500) kcal ME/kg for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than nine hundred (900) kcal ME/kg for products containing sixty-five percent (65%) or more moisture; and

(iii) include on the label feeding directions that reflect a reduction in calorie intake consistent with the intended use.

(B) A cat food product that bears on its label the terms "light", "lite", "low calorie", or words of similar designation shall:

(i) contain no more than three thousand two hundred fifty (3,250) kcal ME/kg for products containing less than twenty percent (20%) moisture, no more than two thousand six hundred fifty (2,650) kcal ME/kg for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than nine hundred fifty (950) kcal ME/kg for products containing sixty-five percent (65%) or more moisture; and

(ii) include on the label a calorie content statement:

(AA) in accordance with the format provided in section 9 of this rule; and

(BB) that states no more than three thousand two hundred fifty (3,250) kcal ME/kg for products containing less than twenty percent (20%) moisture, no more than two thousand six hundred fifty (2,650) kcal ME/kg for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than nine hundred fifty (950) kcal ME/kg for products containing sixty-five percent (65%) or more moisture; and

(iii) include on the label feeding directions which reflect a reduction in calorie intake consistent with the intended use.

(2) "Less" or "reduced calories" requirements are as follows:

(A) A dog or cat food product that bears on its label a claim of "less calories", "reduced calories", or words of similar designation, shall include the following on the label:

(i) The name of the product of comparison and the percentage of calorie reduction (expressed on an equal weight basis) explicitly stated and juxtaposed with the largest or most prominent use of the claim on each panel of the label where the term appears.

(ii) The comparative statement printed in type of the same color and style and at least half the type size used in the claim.

(iii) A calorie content statement in accordance with the format provided in section 9 of this rule.

(iv) Feeding directions that reflect a reduction in calories compared to feeding directions for the product of comparison.

(B) A comparison between products in different categories of moisture content, that is, less than twenty percent (20%), twenty percent (20%) or more but less than sixty-five percent (65%), sixty-five percent (65%) or more, is misleading.

(b) The following are requirements for fat terms:

(1) "Lean" requirements are as follows:

(A) A dog food product that bears on its label the terms "lean", "low fat", or words of similar designation shall:

(i) contain no more than nine percent (9%) crude fat for products containing less than twenty percent (20%) moisture, no more than seven percent (7%) crude fat for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than four percent (4%) crude fat for products containing sixty-five percent (65%) or more moisture; and

(ii) include on the product label in the guaranteed analysis a maximum crude fat guarantee:

(AA) immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in section 4(a)(1) of this rule; and

(BB) that is no more than nine percent (9%) crude fat for products containing less than twenty percent (20%) moisture, no more than seven percent (7%) crude fat for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than four percent (4%) crude fat for products containing sixty-five percent (65%) or more moisture.

(B) A cat food product that bears on its label the terms "lean", "low fat", or words of similar designation shall:

(i) contain a maximum percentage of crude fat which is no more than ten percent (10%) crude fat for products containing less than twenty percent (20%) moisture, no more than eight percent (8%) crude fat for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than five percent (5%) crude fat for products containing sixty-five percent (65%) or more moisture; and

(ii) include on the product label in the guaranteed analysis a maximum crude fat guarantee:

(AA) immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in section 4(a)(1) of this rule; and

(BB) that is no more than ten percent (10%) crude fat for products containing less than twenty percent (20%) moisture, no more than eight percent (8%) crude fat for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than five percent (5%) crude fat for products containing sixty-five percent (65%) or more moisture.

(2) "Less" or "reduced fat" requirements for a dog or cat food product that bears on its label a claim of "less fat", "reduced fat", or words of similar designation, shall include the following on the label:

(A) The name of the product of comparison and the percentage of fat reduction (expressed on an equal weight basis) explicitly stated and juxtaposed with the largest or most prominent use of the claim on each panel of the label on where the term appears.

(B) The comparative statement printed in type of the same color and style and at least half the type size used in the claim.

(C) A maximum crude fat guarantee in the guaranteed analysis immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in section 4(a)(1) of this rule.

(c) A comparison on the label between products in different categories of moisture content, that is, less than twenty percent (20%), twenty percent (20%) or more but less than sixty-five percent (65%), sixty-five percent (65%) or more, is misleading. *(State Chemist of the State of Indiana; 355 IAC 6-2-10; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2460)*

355 IAC 6-2-11 Manufacturer or distributor; name and address

Authority: IC 15-5-13-14
Affected: IC 15-5-13-6

Sec. 11. (a) The label of a pet food or specialty pet food shall specify the name and address of the manufacturer or distributor. The statement of the place of business shall include the street address, city, state, and zip code; however, the street address may be omitted if such street address is shown in a current city directory or telephone directory for the city listed on the label.

(b) When a person manufactures or distributes a pet food or specialty pet food in a place other than the principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such pet food or specialty pet food was manufactured or package or from where each package is to be distributed. *(State Chemist of the State of Indiana; 355 IAC 6-2-11; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2462)*

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TITLE 405 OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES

LSA Document #00-277(F)

DIGEST

Amends 405 IAC 1-14.6-2, 405 IAC 1-14.6-3, 405 IAC 1-14.6-4, 405 IAC 1-14.6-5, 405 IAC 1-14.6-6, 405 IAC 1-14.6-7, 405 IAC 1-14.6-9, and 405 IAC 1-14.6-20 to revise case mix reimbursement methodology by modifying the payment methodology for therapy, for repairs and maintenance costs, reduce the profit-add-on percentage, and update case mix indices. Amends 405 IAC 1-15-1, 405 IAC 1-15-5, and 405 IAC 1-15-6 to clarify when MDS assessments are due at the conclusion of therapies and to make technical changes. *NOTE: Under IC 4-22-2-40, LSA Document #00-277, printed at 24 IR 3169, was recalled by the Office of the Secretary of Family and Social Services. This document is a revised version of the recalled document.* Effective 30 days after filing with the secretary of state.

405 IAC 1-14.6-2
405 IAC 1-14.6-3
405 IAC 1-14.6-4
405 IAC 1-14.6-5
405 IAC 1-14.6-6
405 IAC 1-14.6-7
405 IAC 1-14.6-9
405 IAC 1-14.6-20
405 IAC 1-15-1
405 IAC 1-15-5
405 IAC 1-15-6

SECTION 1. 405 IAC 1-14.6-2 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-14.6-2 Definitions

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 2. (a) As used in this rule, "administrative component" means the portion of the Medicaid rate that shall reimburse providers for allowable administrative services and supplies, including prorated employee benefits based on salaries and wages. Administrative services and supplies include the following:

(1) Administrator and co-administrators, owners' compensation (including directors fees) for patient-related services.
(2) Services and supplies of a home office that are allowable and patient related and are appropriately allocated to the nursing facility.
(3) Office and clerical staff.
(4) Legal and accounting fees.
(5) Advertising.
(6) Travel.
(7) Telephone.
(8) License dues and subscriptions.
(9) Office supplies.
(10) Working capital interest.
(11) State gross receipts taxes.
(12) Utilization review costs.
(13) Liability insurance.
(14) Management and other consultant fees.
(15) Qualified mental retardation professional (QMRP).

(b) As used in this rule, "allowable per patient day cost" means a ratio between allowable cost and patient days.

(c) As used in this rule, "annual financial report" refers to a presentation of financial data, including appropriate supplemen-

tal data, and accompanying notes, derived from accounting records and intended to communicate the provider's economic resources or obligations at a point in time, or changes therein for a period of time in compliance with the reporting requirements of this rule.

(d) As used in this rule, "average allowable cost of the median patient day" means the allowable per patient day cost (including any applicable inflation adjustment) of the median patient day from all providers when ranked in numerical order based on average allowable cost. The average allowable cost (including any applicable inflation adjustment) shall be computed on a statewide basis and shall be maintained by the office with revisions made four (4) times per year effective January 1, April 1, July 1, and October 1.

(e) As used in this rule, "average historical cost of property of the median bed" means the allowable patient-related property per bed for facilities that are not acquired through an operating lease arrangement, when ranked in numerical order based on the allowable patient-related historical property cost per bed that shall be updated each calendar quarter. Property shall be considered allowable if it satisfies the conditions of section 14(a) of this rule.

(f) As used in this rule, "calendar quarter" means a three (3) month period beginning January 1, April 1, July 1, or October 1.

(g) As used in this rule, "capital component" means the portion of the Medicaid rate that shall reimburse providers for the use of allowable capital-related items. Such capital-related items include the following:

(1) The fair rental value allowance.
(2) Property taxes.
(3) Property insurance.
~~(4) Repairs and maintenance.~~

(h) As used in this rule, "case mix index" (CMI) means a numerical value score that describes the relative resource use for each resident within the groups under the Resource Utilization Group (RUG-III) classification system prescribed by the office based on an assessment of each resident. The facility CMI shall be based on the resident CMI, calculated on a facility-average, time-weighted basis for the following:

(1) Medicaid residents.
(2) All residents.

~~This information shall be made available to the provider for purposes of tracking the facility's CMI.~~

(i) As used in this rule, "cost center" means a cost category delineated by cost reporting forms prescribed by the office.

(j) As used in this rule, "delinquent MDS resident assessment" means an assessment that is not electronically transmitted ~~to the office or its contractor~~ by the fifteenth day of the second month following the end of a calendar quarter, or an assessment that is greater than one hundred thirteen (113) days old, as measured by the R2b date field on the MDS.

(k) As used in this rule, "desk audit" means a review of a written audit report and its supporting documents by a qualified auditor, together with the auditor's written findings and recommendations.

(l) As used in this rule, "direct care component" means the portion of the Medicaid rate that shall reimburse providers for allowable direct patient care services and supplies, including prorated employee benefits based on salaries and wages. Direct care services and supplies include all:

(1) nursing and nursing aide services;
(2) nurse consulting services;
(3) pharmacy consultants;
(4) medical director services;
(5) nurse aide training;
(6) medical supplies;
(7) oxygen; **and**
~~(8) therapy services; and~~
~~(9)~~ **(8)** medical records costs.

(m) As used in this rule,"fair rental value allowance" means a methodology for reimbursing nursing facilities for the use of allowable facilities and equipment, based on establishing a rental valuation on a per bed basis of such facilities and equipment, and a rental rate.

(n) As used in this rule, "field audit" means a formal official verification and methodical examination and review, including the final written report of the examination of original books of accounts and resident assessment data and its supporting documentation by auditors.

(o) As used in this rule, "forms prescribed by the office" means cost reporting forms provided by the office or substitute forms that have received prior written approval by the office.

(p) As used in this rule, "general line personnel" means management personnel above the department head level who perform a policymaking or supervisory function impacting directly on the operation of the facility.

(q) As used in this rule, "generally accepted accounting principles" or "GAAP" means those accounting principles as established by the American Institute of Certified Public Accountants.

~~(r) As used in this rule, "inaccurate MDS resident assessment" means an assessment where one (1) or more data items that are required to classify a resident pursuant to the RUG-III resident classification system is not supported according to the MDS supporting documentation guidelines as set forth in 405 IAC 1-15.~~

~~(s)~~ **(r)** As used in this rule, "incomplete MDS resident

assessment" means an assessment that does not contain all data items that are required to classify a resident pursuant to the RUG-III resident classification system, ~~(e.g.,~~ **for example,** MDS RUG fields that include blanks, out-of-range, or inconsistent responses, or an assessment that is not printed by the nursing facility provider upon request by the office or its contractor.

~~(t)~~ **(s)** As used in this rule, "indirect care component" means the portion of the Medicaid rate that shall reimburse providers for allowable indirect patient care services and supplies, including prorated employee benefits based on salaries and wages. Indirect care services and supplies include the following:

(1) Allowable dietary services and supplies.
(2) Raw food.
(3) Patient laundry services and supplies.
(4) Patient housekeeping services and supplies.
(5) Plant operations services and supplies.
(6) Utilities.
(7) Social services.
(8) Activities supplies and services.
(9) Recreational supplies and services.
(10) Repairs and maintenance.

~~(u)~~ **(t)** As used in this rule, "minimum data set (MDS)" means a core set of screening and assessment elements, including common definitions and coding categories, that form the foundation of the comprehensive assessment for all residents of long term care facilities certified to participate in the Medicaid program. The items in the MDS standardize communication about resident problems, strengths, and conditions within facilities, between facilities, and between facilities and outside agencies. Version 2.0 (1/30/98) is the most current form to the minimum data set (MDS 2.0). The Indiana system will employ the MDS 2.0 or subsequent revisions as approved by the **Centers for Medicare & Medicaid Services (CMS), formerly the** Health Care Financing Administration.

~~(v)~~ **(u)** As used in this rule, "medical and nonmedical supplies and equipment" include those items generally required to assure adequate medical care and personal hygiene of patients.

~~(w)~~ **(v)** As used in this rule, "normalized allowable cost" means total allowable direct patient care costs for each facility divided by that facility's average case mix index (CMI) for all residents.

~~(x)~~ **(w)** As used in this rule, "office" means the office of Medicaid policy and planning.

~~(y)~~ **(x)** As used in this rule, "ordinary patient-related costs" means costs of allowable services and supplies that are necessary in delivery of patient care by similar providers within the state.

~~(z)~~ **(y)** As used in this rule, "patient/recipient care" means those Medicaid program services delivered to a Medicaid enrolled recipient by a certified Medicaid provider.

~~(aa)~~ **(z)** As used in this rule, "reasonable allowable costs" means the price a prudent, cost conscious buyer would pay a willing seller for goods or services in an arm's-length transaction, not to exceed the limitations set out in this rule.

~~(bb)~~ **(aa)** As used in this rule, "related party/organization" means that the provider is associated or affiliated with, or has the ability to control, or be controlled by, the organization furnishing the service, facilities, or supplies, whether or not such control is actually exercised.

~~(cc)~~ **(bb)** As used in this rule, "RUG-III resident classification system" means the resource utilization group used to classify residents. **When a resident classifies into more than one (1) RUG III group, the RUG III group with the greatest CMI will be utilized to calculate the facility-average CMI and facility-average CMI for Medicaid residents.**

(cc) As used in this rule, "therapy component" means the portion of each facility's direct costs for therapy services, including any employee benefits prorated based on total salaries and wages, rendered to Medicaid residents that are not reimbursed by other payors, as determined by this rule.

(dd) As used in this rule, "unit of service" means all patient care included in the established per diem rate required for the care of an inpatient for one (1) day (twenty-four (24) hours).

(ee) As used in this rule, "unsupported MDS resident assessment" means an assessment where one (1) or more data items that are required to classify a resident pursuant to the RUG-III resident classification system is not supported according to the MDS supporting documentation guidelines as set forth in 405 IAC 1-15.

~~(ee)~~ **(ff)** As used in this rule, "untimely MDS resident assessment" means a significant change MDS assessment, as defined by ~~HCFA's~~ **CMS'** Resident Assessment Instrument (RAI) Manual, that is not completed within fourteen (14) days of determining that a nursing facility resident's condition has changed significantly; or a full **or quarterly** MDS assessment that is not completed as required by 405 IAC 1-15-6(a) following the conclusion of all physical therapy, speech therapy, and occupational therapy. *(Office of the Secretary of Family and Social Services; 405 IAC 1-14.6-2; filed Aug 12, 1998, 2:27 p.m.: 22 IR 69, eff Oct 1, 1998; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2238; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2462)*

SECTION 2. 405 IAC 1-14.6-3 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-14.6-3 Accounting records; retention schedule; audit trail; accrual basis; segregation of accounts by nature of business and by location

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 3. (a) Generally accepted accounting principles shall be followed in the preparation and presentation of all financial reports and all reports detailing change of provider transactions unless otherwise prescribed by this rule.

(b) Each provider must maintain financial records for a period of three (3) years after the date of submission of financial reports to the office. The accrual basis of accounting shall be used in all data submitted to the office except for government operated providers that are otherwise required by law to use a cash system. The provider's accounting records must establish an audit trail from those records to the financial reports submitted to the office.

(c) In the event that a field audit indicates that the provider's records are inadequate to support data submitted to the office and the auditor is unable to complete the audit and issue an opinion, the provider shall be given, in writing, a list of the deficiencies and allowed sixty (60) days from the date of receipt of this notice to correct the deficiencies. In the event the deficiencies are not corrected within the sixty (60) day period, the office shall not grant any rate increase to the provider until the cited deficiencies are corrected and notice is sent to the office by the provider. However, the office may:

(1) make appropriate adjustments to the applicable cost reports of the provider resulting from inadequate records;

(2) document such adjustments in a finalized exception report; and

(3) incorporate such adjustments in prospective rate calculations under subsection (d).

(d) Each provider shall submit ~~upon request,~~ confirmation that all deficiencies and adjustments noted in the field audit final written report have been corrected and are not present in the current period annual financial report. However, if deficiencies and adjustments are not corrected, the office may make appropriate adjustments to current and subsequent cost reports of the provider.

(e) If a provider has business enterprises or activities other than those reimbursed by Medicaid under this rule, the revenues, expenses, and statistical and financial records for such enterprises or activities shall be clearly identifiable from the records of the operations reimbursed by Medicaid. If a field or desk audit establishes that records are not maintained so as to clearly identify Medicaid information, none of the commingled costs shall be recognized as Medicaid allowable costs.

(f) When multiple facilities or operations are owned by a single entity with a central office, the central office records shall be maintained as a separate set of records with costs and revenues separately identified and appropriately allocated to individual facilities. Each central office entity shall file an annual financial report coincidental with the time period for any individual facility that receives any central office allocation. Allocation of central office costs shall be reasonable, conform to GAAP, and be consistent between years. Any change of central office allocation bases must be approved by the office prior to the changes being implemented. Proposed changes in allocation methods must be submitted to the office at least ninety (90) days prior to the reporting period to which the change applies. Such costs are allowable only to the extent that the central office is providing services related to patient care and the provider can demonstrate that the central office costs improve efficiency, economy, and quality of recipient care. The burden of demonstrating that costs are patient-related lies with the provider. *(Office of the Secretary of Family and Social Services; 405 IAC 1-14.6-3; filed Aug 12, 1998, 2:27 p.m.: 22 IR 71, eff Oct 1, 1998; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2465)*

SECTION 3. 405 IAC 1-14.6-4 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-14.6-4 Financial report to office; annual schedule; prescribed form; extensions; penalty for untimely filing

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 4. (a) Each provider shall submit an annual financial report to the office not later than ninety (90) days after the close of the provider's reporting year. The annual financial report shall coincide with the fiscal year used by the provider to report federal income taxes for the operation unless the provider requests in writing that a different reporting period be used. Such a request shall be submitted within sixty (60) days after the initial certification of a provider. This option may be exercised only one (1) time by a provider. If a reporting period other than the tax year is established, audit trails between the periods are required, including reconciliation statements between the provider's records and the annual financial report.

(b) The first annual Financial Report for Nursing Facilities for a provider that has undergone a change of provider ownership or control through an arm's-length transaction between unrelated parties shall coincide with that provider's first fiscal year end in which the provider has a minimum of six (6) full calendar months of actual historical financial data. **The provider shall submit their first annual financial report to the office not later than ninety (90) days after the close of the provider's reporting year or thirty (30) days following notification that the change of provider ownership has been reviewed by the office or its contractor. Any extension granted under this section may not exceed an additional**

ninety (90) days, for a total of one hundred eighty (180) days after the close of the provider's reporting year.

(c) The provider's annual financial report shall be submitted using forms prescribed by the office. All data elements and required attachments shall be completed so as to provide full financial disclosure and shall include the following as a minimum:

(1) Patient census data.

(2) Statistical data.

(3) Ownership and related party information.

(4) Statement of all expenses and all income, excluding non-Medicaid routine income.

(5) Detail of fixed assets and patient-related interest bearing debt.

(6) Complete balance sheet data.

(7) Schedule of Medicaid and private pay charges in effect on the last day of the reporting period. Private pay charges shall be the lowest usual and ordinary charge.

(8) Certification by the provider that:

(A) the data are true, accurate, related to patient care; and

(B) expenses not related to patient care have been clearly identified.

(9) Certification by the preparer, if different from the provider, that the data were compiled from all information provided to the preparer by the provider, and as such are true and accurate to the best of the preparer's knowledge.

(d) Extension of the ninety (90) day filing period shall not be granted unless the provider substantiates to the office circumstances that preclude a timely filing. Requests for extensions shall be submitted to the office, prior to the date due, with full and complete explanation of the reasons an extension is necessary. The office shall review the request for extension and notify the provider of approval or disapproval within ten (10) days of receipt. If the request for extension is disapproved, the report shall be due twenty (20) days from the date of receipt of the disapproval from the office. Any extension granted under this section may not exceed an additional ninety (90) days, for a total of one hundred eighty (180) days after the close of the provider's reporting year.

(e) Failure to submit an annual financial report within the time limit required shall result in the following actions:

(1) No rate review shall be accepted or acted upon by the office until the delinquent report is received.

(2) When an annual financial report is thirty (30) days past due and an extension has not been granted, the rate then currently being paid to the provider shall be reduced by ten percent (10%), effective on the first day of the month following the thirtieth day the annual financial report is past due, and shall so remain until the first day of the month after the delinquent annual financial report is received by the office. No rate adjustments will be allowed until the first day of the calendar quarter following receipt of the delinquent annual financial report. Reimbursement lost because of the penalty cannot be recovered by the provider.

(f) Nursing facilities are required to electronically transmit MDS resident assessment information ~~to the office or its contractor~~ in a complete, accurate, and timely manner. **MDS resident assessment information for a calendar quarter must be transmitted by the fifteenth day of the second month following the end of that calendar quarter. Extension of the electronic MDS assessment transmission due date may be granted by the office to a new operation attempting to submit MDS assessments for the first time if the new operation is not currently enrolled or submitting MDS assessments under the Medicare program and the provider can substantiate to the office circumstances that preclude timely electronic transmission.**

(g) Residents discharged prior to completing an initial assessment that is not preceded by a Medicare assessment, or a regularly scheduled assessment will be classified in one (1) of the following RUG-III classifications:

(1) SSB classification for residents discharged before completing an initial assessment where the reason for discharge was death or transfer to hospital.

(2) CC1 classification for residents discharged before completing an initial assessment where the reason for discharge was other than death or transfer to hospital.

(3) The classification from their immediately preceding assessment for residents discharged before completing a regularly scheduled assessment.

(h) If the office or its contractor determines that a nursing facility has transmitted incomplete MDS resident assessments, then, for purposes of determining the facility's CMI, such assessment(s) shall be assigned the case mix index associated with the RUG-III group "BC1 - Unclassifiable".

(i) If the office or its contractor determines that a nursing facility has delinquent MDS resident assessments, then, for purposes of determining the facility's CMI, such assessment(s) shall be assigned the case mix index associated with the RUG-III group "BC2 - Delinquent".

(j) If the office or its contractor determines due to an MDS field audit that a nursing facility has untimely MDS resident assessments, then such assessment(s) shall be counted as an ~~error~~ **unsupported assessment** for purposes of determining whether a corrective remedy shall be applied under subsection (k).

(k) If the office or its contractor determines due to an MDS field audit that a nursing facility has ~~inaccurate~~ **unsupported** MDS resident assessments, then the following procedures shall be followed in applying any corrective remedy:

(1) The office or its contractor shall audit a sample of MDS resident assessments and will determine the percent of

assessments in the sample that are ~~inaccurate or untimely.~~ **unsupported.**

(2) If the percent of assessments in the sample that are ~~inaccurate or untimely~~ **unsupported** is greater than the threshold percent as shown in column (B) of the table below, the office or its contractor shall expand the scope of the MDS audit to all residents. If the percent of assessments in the sample that are ~~inaccurate or untimely~~ **unsupported** is equal to or less than the threshold percent as shown in column (B) of the table below, the office or its contractor shall conclude the MDS audit and no corrective remedy shall be applied.

(3) For nursing facilities with MDS audits performed on all residents, the office or its contractor will determine the percent of assessments audited that are ~~inaccurate or untimely.~~ **unsupported.**

(4) If the percent of assessments of all residents that are ~~inaccurate or untimely~~ **unsupported** is greater than the threshold percent as shown in column (B) of the table below, a corrective remedy shall apply, which shall be calculated as follows. The administrative component portion of the Medicaid rate in effect for the calendar quarter following completion of the MDS audit shall be reduced by the percentage as shown in column (C) of the table below. In the event a corrective remedy is imposed, for purposes of determining the average allowable cost of the median patient day for the administrative component, there shall be no adjustment made by the office or its contractor to the provider's allowable administrative costs. Reimbursement lost as a result of any corrective remedies shall not be recoverable by the provider.

(5) If the percent of assessments of all residents that are ~~inaccurate or untimely~~ **unsupported** is equal to or less than the threshold percent as shown in column (B) of the table below, the office or its contractor shall conclude the audit and no corrective remedy shall apply.

(6) The threshold percent and the administrative component corrective remedy percent in columns (B) and (C) of the table ~~below,~~ **in this subdivision,** respectively, shall be applied to audits begun by the office or its contractor on or after the effective date as stated in column (A) ~~of the table below:~~ **as follows:**

Effective Date (A)	Threshold Percent (B)	Administrative Component Corrective Remedy Percent (C)
October 1, ~~1999~~ **2002**	~~50%~~ **40%**	5%
January 1, ~~2001~~ **2004**	~~35%~~ **30%**	10%
April 1, ~~2002~~ **2005**	20%	15%

(l) Based on findings from the MDS audit, beginning on the effective date of this rule, the office or its contractor shall make adjustments or revisions to all MDS data items that are required to classify a resident pursuant to the RUG-III resident classification system that are not supported according to the MDS supporting documentation guidelines as set forth in 405 IAC 1-15. Such adjustments or revisions to MDS data transmitted by the nursing facility will be made in order to reflect the resident's highest functioning level that is supported according to the MDS supporting documentation guidelines as set forth in 405 IAC 1-15. The resident assessment will then be used to reclassify the resident pursuant to the RUG-III resident classification system by incorporating any adjustments or revisions made by the office or its contractor.

(m) Beginning on the effective date of this rule, upon conclusion of an MDS audit, the office or its contractor shall recalculate the facility's CMI. If the recalculated CMI results in a change to the established Medicaid rate, the rate shall be recalculated and any payment adjustment shall be made. *(Office of the Secretary of Family and Social Services; 405 IAC 1-14.6-4; filed Aug 12, 1998, 2:27 p.m.: 22 IR 72, eff Oct 1, 1998; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2240; errata filed Jun 21, 1999, 12:25 p.m.: 22 IR 3419; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2465)*

SECTION 4. 405 IAC 1-14.6-5 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-14.6-5 New provider; initial financial report to office; criteria for establishing initial interim rates

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 5. (a) Rate requests to establish an initial interim rate for a new operation shall be filed by submitting an initial rate request to the office on or before thirty (30) days after notification of the certification date. Initial interim rates will be set at the sum of the average allowable cost of the median patient day for the direct care, **therapy,** indirect care, administrative, and **eighty percent (80%) of the** capital ~~components.~~ **component.** Prior to the provider's first annual rate review, the direct care component of the Medicaid initial interim rate will be adjusted retroactively to reflect changes, occurring in the first and second **calendar** quarters of operation, in the provider's case mix index for Medicaid residents and adjusted prospectively after the second **calendar** quarter to reflect changes in the provider's case mix index for Medicaid residents. Initial interim rates shall be effective on the certification date or the date that a service is established, whichever is later. In determining the initial rate, limitations and restrictions otherwise outlined in this rule shall apply.

(b) Prior to the first annual rate review, the rate will be adjusted effective on each calendar quarter pursuant to section 6(d) of this rule to account for changes in the provider's case mix index for Medicaid residents. **A provider will not receive a change in** the **medians for calculating its reimbursement rate until its** first annual rate review, **which** shall coincide with the provider's first fiscal year end that occurs after the initial interim rate effective date in which the provider has a minimum of six (6) months of actual historical data.

(c) In the event of a change in nursing facility provider

ownership, ownership structure (including mergers, exchange of stock, etc.), provider, operator, lessor/lessee, or any change in control, a completed Checklist of Management Representations Concerning Change in Ownership shall be submitted to the office or its contractor. The completed checklist shall include all supporting documentation. No Medicaid rate adjustments for the nursing facility shall be performed until the completed checklist is submitted to the office or its contractor. *(Office of the Secretary of Family and Social Services; 405 IAC 1-14.6-5; filed Aug 12, 1998, 2:27 p.m.: 22 IR 73, eff Oct 1, 1998; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2242; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2467)*

SECTION 5. 405 IAC 1-14.6-6 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-14.6-6 Active providers; rate review; requests due to change in law

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 6. (a) The normalized average allowable cost of the median patient day for the direct care component, and the average allowable cost of the median patient day for the indirect, administrative and capital components shall be determined once per year for each provider for the purpose of performing the provider's annual rate review.

(b) The normalized allowable per patient day cost for direct care, and the allowable per patient day costs for the **therapy,** indirect care, administrative, and capital components shall be established once per year for each provider based on the annual financial report.

(c) The rate effective date of the annual rate review shall be the first day of the second calendar quarter following the provider's reporting year end.

(d) Subsequent to the annual rate review, the direct care component of the Medicaid rate will be adjusted quarterly to reflect changes in the provider's case mix index for Medicaid residents. If the facility has no Medicaid residents during a quarter, the facility's average case mix index for all residents will be used in lieu of the case mix index for Medicaid residents. This adjustment will be effective on the first day of each of the following three (3) calendar quarters beginning after the effective date of the annual rate review.

(e) The case mix index for Medicaid residents in each facility shall be updated each calendar quarter and shall be used to adjust the direct care component that becomes effective on the second calendar quarter following the updated case mix index for Medicaid residents.

(f) All rate-setting parameters and components used to calculate the annual rate review, except for the case mix index for Medicaid residents in that facility, shall apply to the calculation of any change in Medicaid rate that is authorized under subsection (d).

(g) The office may consider changes in federal or state law or regulation during a calendar year to determine whether a significant rate increase is mandated. This review will be considered separately by the office. *(Office of the Secretary of Family and Social Services; 405 IAC 1-14.6-6; filed Aug 12, 1998, 2:27 p.m.: 22 IR 73, eff Oct 1, 1998; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2243; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2468)*

SECTION 6. 405 IAC 1-14.6-7 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-14.6-7 Inflation adjustment; minimum occupancy level; case mix indices

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15-13-6

Sec. 7. (a) For purposes of determining the average allowable cost of the median patient day and a provider's annual rate review, each provider's cost from the most recent completed year will be adjusted for inflation by the office using the methodology in this subsection. All allowable costs of the provider, except for mortgage interest on facilities and equipment, depreciation on facilities and equipment, rent or lease costs for facilities and equipment, and working capital interest shall be ~~increased~~ **adjusted** for inflation using the Health Care Financing Administration/Skilled Nursing Facility (HCFA/SNF) index as published by DRI/McGraw-Hill. The inflation adjustment shall apply from the midpoint of the annual financial report period to the midpoint prescribed as follows:

Effective Date	Midpoint Quarter
January 1, Year 1	July 1, Year 1
April 1, Year 1	October 1, Year 1
July 1, Year 1	January 1, Year 2
October 1, Year 1	April 1, Year 2

(b) Notwithstanding subsection (a), beginning on the effective date of this rule through September 30, 2003, the inflation adjustment determined as prescribed in subsection (a) shall be reduced by an inflation reduction factor equal to three and three-tenths percent (3.3%). The resulting inflation adjustment shall not be less than zero (0). Prior to September 30, 2003, the office may reduce or eliminate the inflation reduction factor to increase aggregate expenditures up to levels appropriated by the Indiana general assembly. Any reduction or elimination of the inflation reduction factor shall be made effective no earlier than permitted under IC 12-15-13-6(a).

~~(b)~~ **(c)** In determining prospective allowable costs for a new

provider that has undergone a change of provider ownership or control through an arm's-length transaction between unrelated parties, when the first fiscal year end following the change of provider ownership or control is less than six (6) full calendar months, the previous provider's most recently completed annual financial report **for which a rate has been established** shall be utilized to calculate the new provider's first annual rate review. The inflation adjustment for the new provider's first annual rate review shall be applied from the midpoint of the previous provider's most recently completed annual financial report period to the midpoint prescribed under subsection (a).

~~(c)~~ **(d)** The normalized average allowable cost of the median patient day for direct care costs and the average allowable cost of the median patient day for indirect care, administrative and capital-related costs shall not be less than the average allowable cost of the median patient day ~~calculated at the time of implementation of this rule.~~ **effective October 1, 1998.**

~~(d)~~ **(e)** Allowable costs per patient day for capital-related costs shall be computed based on an occupancy level equal to the greater of ninety-five percent (95%), or the provider's actual occupancy from the most recently completed historical period.

~~(e)~~ **(f)** The case mix indices (CMIs) contained ~~in column A~~ in this subsection shall be used for purposes of determining each resident's CMI used to calculate the facility-average CMI for all residents, ~~The CMIs contained in column B in this subsection shall be used for purposes of determining each Medicaid resident's CMI used to calculate~~ **and** the facility-average CMI for Medicaid residents. ~~except for Medicaid residents who are not eligible for Medicare Part B benefits, in which case the CMIs contained in column A shall be used for those residents.~~

RUG-III Group	RUG-II Code	CMI Table ~~A~~	~~B~~
~~Special Rehabilitation~~	~~RVC~~	~~3.35~~	~~2.10~~
~~Special Rehabilitation~~	~~RVB~~	~~2.77~~	~~1.50~~
~~Special Rehabilitation~~	~~RVA~~	~~2.76~~	~~1.32~~
~~Special Rehabilitation~~	~~RHD~~	~~2.68~~	~~2.00~~
~~Special Rehabilitation~~	~~RHC~~	~~2.19~~	~~1.49~~
~~Special Rehabilitation~~	~~RHB~~	~~2.02~~	~~1.39~~
~~Special Rehabilitation~~	~~RHA~~	~~1.91~~	~~1.27~~
~~Special Rehabilitation~~	~~RMC~~	~~2.34~~	~~1.90~~
Special Rehabilitation	~~RMB~~ **RAD**	~~1.83~~ **2.02**	~~1.34~~
Special Rehabilitation	~~RMA~~ **RAC**	~~1.74~~ **1.69**	~~1.27~~
Special Rehabilitation	~~RLB~~ **RAB**	~~1.43~~ **1.50**	~~1.23~~
Special Rehabilitation	~~RLA~~ **RAA**	~~1.27~~ **1.24**	~~1.07~~
Extensive Services	SE3	~~5.06~~ **2.69**	~~5.06~~
Extensive Services	SE2	~~2.91~~ **2.23**	~~2.91~~
Extensive Services	SE1	~~2.05~~ **1.85**	~~2.05~~
Special Care	SSC	~~1.52~~ **1.75**	~~1.52~~
Special Care	SSB	~~1.38~~ **1.60**	~~1.38~~
Special Care	SSA	~~1.35~~ **1.51**	~~1.35~~
~~Clinically Complex~~	~~CD2~~	~~1.20~~	~~1.20~~
~~Clinically Complex~~	~~CD1~~	~~1.15~~	~~1.15~~
Clinically Complex	CC2	~~1.05~~ **1.33**	~~1.05~~
Clinically Complex	CC1	~~0.99~~ **1.27**	~~0.99~~
Clinically Complex	CB2	~~1.02~~ **1.14**	~~1.02~~
Clinically Complex	CB1	~~0.91~~ **1.07**	~~0.91~~
Clinically Complex	CA2	~~0.91~~ **0.95**	~~0.91~~
Clinically Complex	CA1	~~0.77~~ **0.87**	~~0.77~~
Impaired Cognition	IB2	~~0.86~~ **0.93**	~~0.86~~
Impaired Cognition	IB1	~~0.78~~ **0.82**	~~0.78~~
Impaired Cognition	IA2	~~0.69~~ **0.68**	~~0.69~~
Impaired Cognition	IA1	~~0.60~~ **0.62**	~~0.60~~
Behavior Problems	BB2	~~0.86~~ **0.89**	~~0.86~~
Behavior Problems	BB1	0.77	~~0.77~~
Behavior Problems	BA2	~~0.62~~ **0.67**	~~0.62~~
Behavior Problems	BA1	0.54	~~0.54~~
Reduced Physical Functions	PE2	~~0.96~~ **1.06**	~~0.96~~
Reduced Physical Functions	PE1	~~0.92~~ **0.96**	~~0.92~~
Reduced Physical Functions	PD2	~~0.90~~ **0.97**	~~0.90~~
Reduced Physical Functions	PD1	~~0.85~~ **0.87**	~~0.85~~
Reduced Physical Functions	PC2	~~0.78~~ **0.83**	~~0.78~~
Reduced Physical Functions	PC1	~~0.77~~ **0.76**	~~0.77~~
Reduced Physical Functions	PB2	~~0.68~~ **0.73**	~~0.68~~
Reduced Physical Functions	PB1	~~0.63~~ **0.66**	~~0.63~~
Reduced Physical Functions	PA2	~~0.60~~ **0.56**	~~0.60~~
Reduced Physical Functions	PA1	0.50	~~0.50~~
Unclassifiable	BC1	0.48	~~0.48~~
Delinquent	BC2	0.48	~~0.48~~

(g) The office or its contractor shall provide each nursing facility with the following:

(1) Two (2) preliminary CMI reports. These preliminary CMI reports serve as confirmation of the MDS assessments transmitted by the nursing facility, and provide an opportunity for the nursing facility to correct and transmit any missing or incorrect MDS assessments. The first preliminary report will be provided by the seventh day of the first month following the end of a calendar quarter. The second preliminary report will be provided by the seventh day of the second month following the end of a calendar quarter.

(2) Final CMI reports utilizing MDS assessments received by the fifteenth day of the second month following the end of a calendar quarter. These assessments received by the fifteenth day of the second month following the end of a calendar quarter will be utilized to establish the facility-average CMI and facility-average CMI for Medicaid residents utilized in establishing the nursing facility's Medicaid rate.

(h) The office may increase Medicaid reimbursement to nursing facilities that provide inpatient services to more than eight (8) ventilator-dependent residents. Additional reimbursement shall be made to such facilities at a rate of eight dollars and seventy-nine cents ($8.79) per Medicaid resident day. *(Office of the Secretary of Family and Social Services; 405 IAC 1-14.6-7; filed Aug 12, 1998, 2:27 p.m.: 22 IR 74, eff Oct 1, 1998; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2243; readopted filed Jun 27, 2001, 9:40 a.m.:24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2468)*

SECTION 7. 405 IAC 1-14.6-9 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-14.6-9 Rate components; rate limitations; profit add-on

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15-13-6

Sec. 9. (a) The Medicaid reimbursement system is based on recognition of the provider's allowable costs for the direct care, **therapy,** indirect care, administrative and capital components, plus a potential profit add-on payment. The direct care, **therapy,** indirect care, administrative, and capital rate components are calculated as follows:

(1) The indirect care, administrative, and capital components, are equal to the provider's allowable per patient day costs for each component, plus the allowed profit add-on payment as determined by the methodology in subsection ~~9(b).~~ **(b).**

(2) The therapy component is equal to the provider's allowable per patient day costs.

~~(2)~~ **(3)** The direct care component is equal to the provider's normalized allowable per patient day costs times the facility-average case mix index for Medicaid residents, plus the allowed profit add-on payment as determined by the methodology in subsection ~~9(b).~~ **(b).**

(b) The profit add-on payment will be calculated as follows:

(1) For the direct care component, the profit add-on is equal to ~~sixty~~ **fifty-two** percent ~~(60%)~~ **(52%)** of the difference (if greater than zero (0)) of:

(A) the normalized average allowable cost of the median patient day for direct care costs times the facility average case mix index for Medicaid residents times one hundred five percent (105%); minus

(B) a provider's normalized allowable per patient day costs times the facility average case mix index for Medicaid residents.

(2) For the indirect care component, the profit add-on is equal to ~~sixty~~ **fifty-two** percent ~~(60%)~~ **(52%)** of the difference (if greater than zero (0)) of:

(A) the average allowable cost of the median patient day times one hundred percent (100%); minus

(B) a provider's allowable per patient day cost.

(3) For the administrative component, the profit add-on is equal to sixty percent (60%) of the difference (if greater than zero (0)) of:

(A) the average allowable cost of the median patient day times one hundred percent (100%); minus

(B) a provider's allowable per patient day cost.

(4) For the capital component, the profit add-on is equal to sixty percent (60%) of the difference (if greater than zero (0)) of:

(A) the average allowable cost of the median patient day times eighty percent (80%); minus

(B) a provider's allowable per patient day cost.

(5) For the therapy component, the profit add-on is equal to zero (0).

(c) Notwithstanding subsections (a) and (b), in no instance shall a rate component exceed the overall rate component limit defined as follows:

(1) The normalized average allowable cost of the median patient day for direct care costs, times the facility-average case mix index for Medicaid residents times one hundred ten percent (110%).

(2) The average allowable cost of the median patient day for indirect care costs times one hundred percent (100%).

(3) The average allowable cost of the median patient day for administrative costs times one hundred percent (100%).

(4) The average allowable cost of the median patient day for capital-related costs times eighty percent (80%).

(5) For the therapy component, no overall rate component limit shall apply.

(d) In order to determine the normalized allowable direct care costs from each facility's Financial Report for Nursing Facilities, ~~beginning with the first financial report submitted to the office or its contractor under this rule,~~ the office or its contractor shall determine each facility's CMI for all residents on a time-weighted basis.

(e) The office shall publish guidelines for use in determining the time-weighted CMI. These guidelines shall be published as a provider bulletin and may be updated by the office as needed. Any such updates shall be made effective no earlier than permitted under IC 12-15-13-6(a). *(Office of the Secretary of Family and Social Services; 405 IAC 1-14.6-9; filed Aug 12, 1998, 2:27 p.m.: 22 IR 75, eff Oct 1, 1998; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2244; readopted filed Jun 27, 2001, 9:40 a.m.:24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2470)*

SECTION 8. 405 IAC 1-14.6-20 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-14.6-20 Nursing facilities reimbursement for therapy services

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 20. (a) Therapy services provided to Medicaid recipients by nursing facilities are included in the established rate. Under no circumstances shall therapies for nursing facility residents be billed to Medicaid through any provider. Therapy services for

nursing facility residents that are reimbursed by other payor sources shall not be reimbursed ~~in the aggregate~~ by Medicaid.

(b) For purposes of determining allowable ~~direct care~~ **therapy** costs, the office or its contractor shall adjust ~~the aggregate~~ **each provider's** cost of therapy services reported on the Nursing Facility Financial Report, **including any employee benefits prorated based on total salaries and wages,** to account for non-Medicaid payers, including Medicare, of therapy services provided to nursing facility residents. Such ~~adjustments~~ **adjustment** shall be applied **to each cost report** in order to remove reported costs attributable ~~in the aggregate~~ to therapy services ~~that may be~~ reimbursed by other payers. The adjustment shall be ~~updated quarterly and applied for rate-setting purposes to all cost reports with rate effective dates beginning on or after the first day of the same calendar quarter.~~ **calculated based on an allocation of reported therapy revenues and shall be subject to field audit verification.** *(Office of the Secretary of Family and Social Services; 405 IAC 1-14.6-20; filed Aug 12, 1998, 2:27 p.m.: 22 IR 81, eff Oct 1, 1998; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2247; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2470)*

SECTION 9. 405 IAC 1-15-1 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-15-1 Scope
Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 1. This section requires nursing facilities certified to provide nursing facility care to Medicaid recipients to electronically transmit minimum data set (MDS) information for all residents, **including residents in a noncertified bed,** to the office of Medicaid policy and planning for use in establishing and maintaining a case mix reimbursement system for Medicaid payments to nursing facilities and other Medicaid program management purposes. *(Office of the Secretary of Family and Social Services; 405 IAC 1-15-1; filed Nov 1, 1995, 8:30 a.m.: 19 IR 350; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2247; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2471)*

SECTION 10. 405 IAC 1-15-5 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-15-5 MDS audit requirements
Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 5. (a) The office or its contractor shall periodically audit the MDS supporting documentation maintained by nursing facilities for all residents, regardless of payer type. Such audits shall be conducted as frequently as deemed necessary by the office, and each nursing facility shall be audited no less frequently than every fifteen (15) months. **Advance notification of up to seventy-two (72) hours shall be provided by the office or its contractor for all MDS audits, except for follow-up audits that are intended to ensure compliance with validation improvement plans. Advance notification for follow-up audits shall not be required.**

(b) The MDS assessments subject to audit will include those assessments most recently transmitted to the office or its contractor in accordance with section 1 of this rule. The office may audit additional MDS assessments if it is deemed necessary. **All supportive documentation to be considered for MDS audit must meet the criteria as specified in Section AA9 on the MDS Version 2.0 Basic Assessment Tracking Form.**

(c) When conducting the MDS audits, the office or its contractor shall consider all MDS supporting documentation that is provided by the nursing facility and is available to the auditors prior to the exit conference. ~~which shall occur at the conclusion of the audit.~~ MDS supporting documentation that is provided by the nursing facility after the exit conference shall not be considered by the office.

(d) The nursing facility shall be required to produce, upon request by the office or its contractor, a computer generated copy of the MDS assessment that is transmitted in accordance with section 1 of this rule, which shall be the basis for the MDS audit.

(e) Suspected intentional alteration of clinical documentation, or creation of documentation after MDS assessments have been transmitted, shall be referred to the Medicaid fraud control unit (MFCU) of the Indiana attorney general's office for investigation of possible fraud. Such an investigation could result in a felony or misdemeanor criminal conviction. *(Office of the Secretary of Family and Social Services; 405 IAC 1-15-5; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2249; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2471)*

SECTION 11. 405 IAC 1-15-6 IS AMENDED TO READ AS FOLLOWS:

405 IAC 1-15-6 MDS assessment requirements
Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 6. Nursing facilities shall complete and transmit to the office or its contractor a new full **or quarterly** MDS assessment for all residents **not in a continuing Medicare Part A stay** after the conclusion of all physical, speech, and occupational therapies. **This requirement only applies when the immediately preceding assessment for a resident classified him/her in the Rehabilitation category.** Such new full **or quarterly** assessments shall be completed in order that the

MDS assessment reference date (A3a) shall be no earlier than eight (8) days and no later than ten (10) days after the conclusion of all physical, speech, and occupational therapies. If the resident expires or is discharged from the facility, no such new full **or quarterly** assessment is required. *(Office of the Secretary of Family and Social Services; 405 IAC 1-15-6; filed Mar 2, 1999, 4:42 p.m.: 22 IR 2249; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:30 p.m.: 25 IR 2471)*

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Incorporated Documents Filed with Secretary of State: None

TITLE 405 OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES

LSA Document #01-206(F)

DIGEST

Amends 405 IAC 2-3-1.1 to specify the method for calculating the Medicaid eligibility penalty for transferring income. Specifies that when the right to a stream of income is transferred for less than fair market value, the penalty is calculated based on the projected total income expected to be transferred during the individual's lifetime. Specifies that a transfer of income includes, but is not limited to: (1) transferring income-producing real property; and (2) accepting less than the fair market rental value when property is rented. Specifies that, for purposes of the Medicaid eligibility penalty for transferring assets for less than fair market value, "assets" includes any income or resources which the applicant or recipient or the applicant's or recipient's spouse is entitled to receive, but does not receive because of failure to take action to receive those assets. Repeals 405 IAC 2-3-1. Effective 30 days after filing with the secretary of state.

405 IAC 2-3-1
405 IAC 2-3-1.1

SECTION 1. 405 IAC 2-3-1.1 IS AMENDED TO READ AS FOLLOWS:

405 IAC 2-3-1.1 Transfer of property; penalty
Authority: IC 12-8-1-9; IC 12-8-6-5; IC 12-13-7-3; IC 12-15-1-10
Affected: IC 12-15-4; IC 12-15-5; IC 12-15-39.6

Sec. 1.1. (a) The following definitions apply throughout this section:

(1) "Assets" includes all income and resources of the applicant or recipient, and of the applicant's or recipient's spouse, including any income or resources which the applicant or recipient or the applicant's or recipient's spouse is entitled to receive but does not receive because of action:

(A) by the applicant or recipient or the applicant's or recipient's spouse;

(B) by a person, including, but not limited to, a court or administrative body, with legal authority to act in place of or on behalf of the applicant or recipient or the applicant's or recipient's spouse; or

(C) by a person, including, but not limited to, a court or administrative body, acting at the direction or upon the request of the applicant or recipient or the applicant's or recipient's spouse.

The term includes assets that an individual is entitled to receive but does not receive because of failure to take action, subject to subsection (i).

(2) "Individual" means an applicant or recipient of Medicaid.

(3) "Institutionalized individual" means an applicant or recipient who is:

(A) an inpatient in a nursing facility;

(B) an inpatient in a medical institution for whom payment is made based on a level of care provided in a nursing facility; or

(C) who is receiving home and community-based waiver services.

(4) "Net income" means the income produced by real property after deducting allowable expenses of ownership. Allowable and nonallowable expenses are as follows:

(A) The following are allowable expenses of ownership if the owner is responsible for the expenses:

(i) Property taxes.
(ii) Interest payments.
(iii) Repairs and maintenance.
(iv) Advertising expenses.
(v) Lawn care.
(vi) Property insurance.
(vii) Trash removal expenses.
(viii) Snow removal expenses.
(ix) Utilities.
(x) Any other expenses of ownership allowed by the Supplemental Security Income program.

(B) The following are not allowable expenses of ownership:

(i) Depreciation.
(ii) Payments on mortgage principal.
(iii) Personal expenses of the owner.
(iv) Mortgage insurance.
(v) Capital expenditures.

~~(4)~~ **(5)** "Noninstitutionalized individual" means an applicant or recipient receiving any of the services described in subsection (e).

(6) "Qualified long term care insurance policy" has the meaning in 760 IAC 2-20-30.

~~(5)~~ **(7)** "Uncompensated value" means the difference between the fair market value of the asset and the value of the consideration received by the applicant or recipient in return for transferring the asset.

(b) A transfer of assets includes any cash, liquid asset, or property ~~which~~ **that** is transferred, sold, given away, or otherwise disposed of as follows:

(1) Transfer includes any total or partial divestiture of control or access, including, but not limited to, any of the following:

(A) Converting an asset from individual to joint ownership.

(B) Relinquishing or limiting the applicant's or recipient's right to liquidate or sell the asset.

(C) Disposing of a portion or a partial interest in the asset while retaining an interest.

(D) Transferring the right to receive income or a stream of income, including, but not limited to, income produced by real property.

(E) Renting or leasing real property.

(F) Waiving the right to receive a distribution from a decedent's estate, or failing to take action to receive a distribution that the individual is entitled to receive by law, subject to subsection (i).

(2) If an applicant or recipient relinquishes ownership or control over a portion of an asset, but retains ownership, control, or an interest in the remaining portion, the portion relinquished is considered transferred.

(3) A transfer of the applicant's or recipient's assets completed by the applicant's or recipient's power of attorney or legal guardian is considered a transfer by the applicant or recipient.

(4) For purposes of this section, in the case of an asset held by an individual in common with another person or persons in a joint tenancy, tenancy in common, or similar arrangement, the asset, or the affected portion of the asset, shall be considered transferred by the applicant or recipient when any action is taken, either by the applicant or recipient or by any other person, that reduces or eliminates the applicant's or recipient's ownership or control of the asset.

(5) This section applies without regard to the exclusion of the home described in 42 U.S.C. 1382b(a)(1).

(c) If an applicant or recipient of Medicaid, or the spouse of an applicant or recipient, disposes of assets for less than fair market value on or after the look-back date specified in this subsection, the applicant or recipient is ineligible for medical assistance for services described in subsections (d) through (e), for a period beginning on the first day of the first month during or after which assets have been transferred for less than fair market value, and which does not occur in any other periods of ineligibility under this section. The ineligibility period is equal to the number of months specified in subsection (f). The look-back date is determined as follows:

(1) In the case of transfers that do not involve a trust, the look-back date is determined as follows:

(A) For an institutionalized individual, the look-back date is thirty-six (36) months before the first date as of which the individual both:

(i) is an institutionalized individual; and

(ii) has applied for medical assistance.

(B) For a noninstitutionalized individual, the look-back date is thirty-six (36) months before the later of:

(i) the date on which the individual applies for medical assistance; or

(ii) the date on which the individual disposes of assets for less than fair market value.

(2) In the case of transfers which involve payments from a trust or portions of a trust that are treated as assets disposed of by an applicant or recipient under section 22(b)(3) or 22(c)(2) of this rule, the look-back date is determined as follows:

(A) For an institutionalized individual, the look-back date is sixty (60) months before the first date as of which the individual both:

(i) is an institutionalized individual; and

(ii) has applied for medical assistance.

(B) For a noninstitutionalized individual, the look-back date is sixty (60) months before the later of:

(i) the date on which the individual applies for medical assistance; or

(ii) the date on which the individual disposes of assets for less than fair market value.

(d) During the penalty period, an institutionalized individual is ineligible for medical assistance for the following services:

(1) Nursing facility services.

(2) A level of care in any institution equivalent to that of nursing facility services.

(3) Home or community-based waiver services.

(e) During the penalty period, a noninstitutionalized individual is ineligible for the following services:

(1) Home health care services.

(2) Home and community care services for functionally disabled elderly individuals.

(3) Personal care services as defined in 42 U.S.C. 1396a(a)(24).

(4) Any other long term care services, including, but not limited to, the services listed in subsection (d).

(f) The number of months of ineligibility shall be equal to the total, cumulative uncompensated value of all assets transferred by the individual, or the individual's spouse, on or after the look-back date specified in subsection (c), divided by the average monthly cost to a private patient of nursing facility services in the geographic area which includes the county where the individual resides at the time of application. As used in this subsection, "geographic area" means the region identified in ~~405 IAC 1-4-2(o).~~ **Section 2640.10.35.20 of the Family and Social Services Administration Program Policy Manual for Cash Assistance, Food Stamps, and Health Coverage.**

(g) This subsection applies to the transfer of a stream of income, including, but not limited to, the transfer of the income generated by income-producing real property. The transfer of income-producing real property is a transfer of a stream of income if the transferor does not retain the right to receive the income generated by the property. The uncompensated value of income transferred is determined by calculating the greater of:

(1) the fair market value; or

(2) the actual amount;

of total net income that the property or other source of income is expected to produce during the lifetime of the transferor, based on life expectancy tables published by the office, and subtracting the income, if any, that the transferor will receive from the property or other source of income after the transfer.

(h) When an individual accepts a rental payment that is less than the fair market rental value for income-producing property, the uncompensated value of the transfer is determined by:

(1) calculating the difference between the fair market rental value and the amount of rent accepted; and

(2) multiplying the difference by the person's life expectancy based on life expectancy tables published by the office.

(i) This subsection applies to a transfer of assets that results from failure to take action to receive assets to which one is entitled to receive by law. No penalty will be imposed if any of the following circumstances applies:

(1) The applicant or recipient, or the individual with legal authority to act on behalf of the applicant or recipient, is unaware of his or her right to receive assets, or becomes aware of the right to receive assets after the deadline for taking action has passed. If the office notifies the applicant or recipient of his or her right to receive assets prior to the deadline for taking action, the individual will be presumed to be aware of his or her right to receive assets unless subdivision (2) applies.

(2) A physician states that the applicant or recipient is not capable of taking action to receive the assets, and there is no guardian or other individual with the authority to act on the applicant's or recipient's behalf.

(3) The expenses of collecting the assets would exceed the value of the assets.

(4) In the case of a surviving spouse who fails to take a statutory share of a deceased spouse's estate, no penalty will be imposed if the deceased spouse has made other equivalent arrangements to provide for a spouse's needs. "Other equivalent arrangements" includes, but is not limited to, a trust established for the benefit of the surviving spouse.

~~(g)~~ **(j)** An applicant or recipient shall not be ineligible for medical assistance under this section if any of the following apply:

(1) The assets transferred were a home, and title to the home was transferred to any of the following persons:

(A) The spouse of the applicant or recipient.

(B) A child of the applicant or recipient who:

(i) is under twenty-one (21) years of age; or

(ii) is blind or disabled as defined in 42 U.S.C. 1382c.

(C) A sibling of the applicant or recipient who has an equity interest in the home and who was residing in the applicant's or recipient's home for a period of at least one (1) year immediately before the date the applicant or recipient becomes an institutionalized individual.

(D) A son or daughter of the applicant or recipient, other than a child described in clause (B), who was residing in the applicant's or recipient's home for a period of at least two (2) years immediately before the date the applicant or recipient becomes an institutionalized individual, and who the office determines has provided care to the applicant or recipient which permitted the applicant or recipient to reside at home rather than in an institution or facility.

(2) The assets were transferred to the applicant's or recipient's spouse or to another for the sole benefit of the applicant's or recipient's spouse.

(3) The assets were transferred from the applicant's or recipient's spouse to another for the sole benefit of the applicant's or recipient's spouse.

(4) The assets were transferred to:

(A) the applicant's or recipient's child who is disabled or blind as defined in 42 U.S.C. 1382c; or

(B) to a trust, including a trust described in section 22(i) of this rule, established solely for the benefit of the applicant's or recipient's child who is disabled or blind as defined in 42 U.S.C. 1382c.

(5) The assets were transferred to a trust, including a trust described in section 22(i) of this rule, established solely for the benefit of an individual under sixty-five (65) years of age who is disabled as defined in 42 U.S.C. 1382c.

(6) The assets transferred are disregarded for eligibility purposes through the use of a qualified long term care insurance policy pursuant to IC 12-15-39.6. If an asset is disregarded through the use of a qualified long term care insurance policy, that asset and any income generated by that asset may be transferred without penalty.

~~(6)~~ **(7)** A satisfactory showing is made to the office, in accordance with standards specified under 42 U.S.C. 1396p(c)(2)(C) by the Secretary of Health and Human Services, that:

(A) the applicant or recipient intended to dispose of the assets at fair market value or for other valuable consideration;

(B) the assets were transferred exclusively for a purpose other than to qualify for medical assistance; or

(C) all assets transferred for less than fair market value have been returned to the applicant or recipient.

~~(7)~~ **(8)** The office may waive the application of this section in cases of undue hardship, but only to the extent required by standards specified under 42 U.S.C. 1396p(c)(2)(D) by the Secretary of Health and Human Services.

~~(h)~~ **(k)** In the case of a transfer by the spouse of an applicant or recipient which results in a period of ineligibility for medical assistance, the office shall apportion the period of ineligibility, or any portion of that period, between the applicant or recipient and the applicant's or recipient's spouse, if the spouse otherwise becomes eligible for medical assistance, as specified in regulations promulgated under 42 U.S.C. 1396p(c)(4) by the Secretary of Health and Human Services.

~~(i) This section applies to transfers of assets made on or after August 11, 1993. Transfers of assets made prior to August 11, 1993, are governed by section 1(i) of this rule.~~ *(Office of the Secretary of Family and Social Services; 405 IAC 2-3-1.1; filed May 1, 1995, 10:45 a.m.: 18 IR 2223; errata filed Jun 9, 1995, 2:30 p.m.: 18 IR 2796; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 13, 2002, 10:09 a.m.: 25 IR 2472)*

SECTION 2. 405 IAC 2-3-1 IS REPEALED.

SECTION 3. **The amendments in this document apply to transfers occurring on or after June 1, 2002.**

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Incorporated Documents Filed with Secretary of State: None

TITLE 405 OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES

LSA Document #01-214(F)

DIGEST

Amends 405 IAC 5-31-8 to eliminate bed hold days for Medicaid certified and enrolled nursing facilities with less than ninety percent (90%) occupancy. Effective 30 days after filing with the secretary of state.

405 IAC 5-31-8

SECTION 1. 405 IAC 5-31-8 IS AMENDED TO READ AS FOLLOWS:

405 IAC 5-31-8 Reservation of nursing facility beds
Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-1-15; IC 12-15-21-2
Affected: IC 12-13-7-3; IC 12-15

Sec. 8. (a) Although it is not mandatory for facilities to reserve beds, Medicaid will reimburse for reserving beds for Medicaid recipients at one-half (½) the per diem rate provided that the criteria as set out in this section are met.

(b) Hospitalization must be ordered by the physician for treatment of an acute condition that cannot be treated in the nursing facility. The total length of time allowed for payment of a reserved bed for a single hospital stay is fifteen (15) days. ~~If the recipient requires hospitalization longer than the fifteen (15) consecutive days, he or she must be discharged from the nursing facility.~~

(c) A leave of absence must be for therapeutic reasons, as prescribed by the attending physician and as indicated in the recipient's plan of care. The total length of time allotted for therapeutic leaves in any calendar year is ~~eighteen (18) days for skilled level of care and~~ thirty (30). ~~days for intermediate level of care.~~ The leave days need not be consecutive.

(d) Although prior authorization by the office is not required to reserve a bed, a physician's order for the hospitalization or therapeutic leave must be on file in the facility.

(e) Requests for reimbursement of nursing facility services shall be expressed in units of full days. A day begins at midnight and ends twenty-four (24) hours later. The midnight-to-midnight method must be used when reporting days of service, even if the health facility uses a different definition for statistical or other purposes. The day of discharge is not covered.

(f) In no instance will Medicaid reimburse a nursing facility for reserving beds for Medicaid recipients when the nursing facility has an occupancy rate of less than ninety percent (90%). For purposes of this rule, the occupancy rate shall be determined by dividing the total number of residents in licensed beds, excluding residential beds, in the nursing facility taken from the midnight census as of the day that a Medicaid recipient takes a leave of absence, by the total number of licensed nursing facility beds, excluding residential beds. *(Office of the Secretary of Family and Social Services; 405 IAC 5-31-8; filed Jul 25, 1997, 4:00 p.m.: 20 IR 3362; filed Sep 27, 1999, 8:55 a.m.: 23 IR 322; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:36 p.m.: 25 IR 2475)*

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Incorporated Documents Filed with Secretary of State: None

TITLE 405 OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES

LSA Document #01-302(F)

DIGEST

Amends 405 IAC 5-34-12 to eliminate bed hold days for hospice recipients when Medicaid certified and enrolled nursing facility occupancy for all residents is less than 90%. Effective 30 days after filing with the secretary of state.

405 IAC 5-34-12

SECTION 1. 405 IAC 5-34-12 IS AMENDED TO READ AS FOLLOWS:

405 IAC 5-34-12 Reservation of beds for hospice recipients in nursing facilities

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-21-2; IC 12-15-40
Affected: IC 12-15

Sec. 12. (a) Although it is not mandatory for providers to reserve beds, Medicaid will reimburse for reserving nursing facility beds for hospice recipients at one-half (½) the room and board payment ~~determined under 405 IAC 1-16-4,~~ provided that the criteria **as set out** in this section are met.

(b) Hospitalization must be ordered by the hospice physician for treatment of an acute condition that cannot be treated in the nursing facility by the hospice provider. The ~~total~~ **maximum** length of time allowed for payment of a reserved bed for a single hospital stay is fifteen (15) days.

(c) A leave of absence must be for therapeutic reasons, as prescribed by the **hospice** attending ~~hospice~~ physician and as indicated in the **hospice** recipient's plan of care. The ~~total~~ **maximum** length of time allotted for therapeutic leave in any calendar year is limited to eighteen (18) days, which need not be consecutive.

(d) Although prior authorization by the office is not required to reserve a bed, the hospice recipient's physician's order for the hospitalization or **therapeutic** leave must be on file in the nursing facility.

(e) In no instance will Medicaid reimburse a nursing facility for reserving nursing facility beds for hospice Medicaid recipients when the nursing facility has an occupancy rate of less than ninety percent (90%). For purposes of this rule, the occupancy rate shall be determined by dividing the total number of residents in licensed beds, excluding residential beds, in the nursing facility taken from the midnight census as of the day that a Medicaid hospice recipient takes a leave of absence, by the total number of licensed nursing facility beds, excluding residential beds. *(Office of the Secretary of Family and Social Services; 405 IAC 5-34-12; filed Mar 9, 1998, 9:30 a.m.: 21 IR 2383; readopted filed Jun 27, 2001, 9:40 a.m.: 24 IR 3822; filed Mar 18, 2002, 3:34 p.m.: 25 IR 2476)*

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TITLE 405 OFFICE OF THE SECRETARY OF FAMILY AND SOCIAL SERVICES

LSA Document #01-304(F)

DIGEST

Adds 405 IAC 1-18 to specify Medicaid reimbursement methodology for Medicare cross-over claims. Effective 30 days after filing with the secretary of state.

405 IAC 1-18

SECTION 1. 405 IAC 1-18 IS ADDED TO READ AS FOLLOWS:

Rule 18. Reimbursement of Medicare Cross-Over Claims

405 IAC 1-18-1 Definitions

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-1-15; IC 12-15-21-2; IC 12-15-21-3
Affected: IC 12-15-13; IC 12-15-14

Sec. 1. (a) The definitions in this section apply throughout this rule.

(b) "Cross-over claim" means a Medicaid claim filed on behalf of a Medicare beneficiary who is also eligible for Medicaid. The term includes claims filed on behalf of beneficiaries who are eligible for Medicaid in any category, including, but not limited to, qualified Medicare beneficiaries (QMBs) and beneficiaries who are eligible for full Medicaid coverage.

(c) "Medicaid allowable amount" means the reimbursement rate for a Medicaid claim as determined under state and federal law and policies. This reimbursement rate shall be the most recent rate on file with the office of Medicaid policy and planning or its contractor at the time a cross-over claim is processed.

(d) "Medicare coinsurance and deductible" means the

Medicare cost-sharing costs described in 42 U.S.C. 1396d(p)(3)(B) through 42 U.S.C. 1396d(p)(3)(D).

(e) "Medicare payment amount" means the amount of payment made by Medicare to the provider for a given claim. It does not include coinsurance amounts or deductibles. *(Office of the Secretary of Family and Social Services; 405 IAC 1-18-1; filed Mar 18, 2002, 3:32 p.m.: 25 IR 2476)*

405 IAC 1-18-2 Reimbursement of nursing facility cross-over claims

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-1-15; IC 12-15-21-2; IC 12-15-21-3
Affected: IC 12-15-14

Sec. 2. (a) Cross-over claims filed by nursing facilities are reimbursed as set out in this section.

(b) If the Medicare payment amount for a claim exceeds or equals the Medicaid allowable amount for that claim, Medicaid reimbursement will be zero (0).

(c) If the Medicaid allowable amount for a claim exceeds the Medicare payment amount for that claim, Medicaid reimbursement is the lesser of:

(1) the difference between the Medicaid allowable amount minus the Medicare payment amount; or

(2) the Medicare coinsurance and deductible, if any, for the claim.

(d) Cross-over claims filed by providers other than nursing facilities are reimbursed as described in section 3 of this rule. *(Office of the Secretary of Family and Social Services; 405 IAC 1-18-2; filed Mar 18, 2002, 3:32 p.m.: 25 IR 2477)*

405 IAC 1-18-3 Reimbursement of cross-over claims filed by providers other than nursing facilities

Authority: IC 12-8-6-5; IC 12-15-1-10; IC 12-15-1-15; IC 12-15-21-2; IC 12-15-21-3
Affected: IC 12-15-13

Sec. 3. (a) Notwithstanding 405 IAC 1-1-3(f)(2), cross-over claims filed by providers other than nursing facilities are reimbursed as set out in this section.

(b) Medicaid reimbursement will be equal to the Medicare coinsurance and deductible, if any, for the claim.

(c) Cross-over claims filed by nursing facilities are reimbursed as described in section 2 of this rule. *(Office of the Secretary of Family and Social Services; 405 IAC 1-18-3; filed Mar 18, 2002, 3:32 p.m.: 25 IR 2477)*

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TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

LSA Document #01-159(F)

DIGEST

Adds 410 IAC 17-9, 410 IAC 17-10, 410 IAC 17-11, 410 IAC 17-12, 410 IAC 17-13, 410 IAC 17-14, 410 IAC 17-15, and 410 IAC 17-16 to protect the health, safety, and welfare of patients, govern the qualifications of applicants for licenses, govern the operating policies, supervision, and maintenance of service records of home health agencies, and govern the procedure for issuing, renewing, denying, or revoking a license to a home health agency. Repeals 410 IAC 17-1.1, 410 IAC 17-2, 410 IAC 17-3, 410 IAC 17-4, 410 IAC 17-5, 410 IAC 17-6, 410 IAC 17-7, and 410 IAC 17-8. Effective 30 days after filing with the secretary of state.

410 IAC 17-1.1	**410 IAC 17-9**
410 IAC 17-2	**410 IAC 17-10**
410 IAC 17-3	**410 IAC 17-11**
410 IAC 17-4	**410 IAC 17-12**
410 IAC 17-5	**410 IAC 17-13**
410 IAC 17-6	**410 IAC 17-14**
410 IAC 17-7	**410 IAC 17-15**
410 IAC 17-8	**410 IAC 17-16**

SECTION 1. 410 IAC 17-9 IS ADDED TO READ AS FOLLOWS:

Rule 9. Definitions

410 IAC 17-9-1 Applicability

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. The definitions in this rule apply throughout this article. *(Indiana State Department of Health; 410 IAC 17-9-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2477)*

410 IAC 17-9-2 "Administrator" defined

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. "Administrator" means any health care professional who has at least one (1) year of supervisory or administrative experience in health service, or any other individual who has at least one (1) year of experience in health service administration or health service finance.

(Indiana State Department of Health; 410 IAC 17-9-2; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2477)

410 IAC 17-9-3 "Advance directive" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. "Advance directive" means a written instruction, such as a living will or durable power of attorney for health care, recognized under state law and relating to the provision of such care when the individual is incapacitated. *(Indiana State Department of Health; 410 IAC 17-9-3; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-4 "Attendant care services" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 4. "Attendant care services" means those services that could be performed by an impaired individual for whom the services are provided if the individual were not impaired, that enable the impaired individual to live in the individual's home and community, rather than in an institution, and to carry out functions of daily living, self care, and mobility. The term includes the following:

(1) Assistance in getting in and out of beds, wheelchairs, and motor vehicles.

(2) Assistance with routine bodily functions, including the following:

(A) Bathing and personal hygiene.

(B) Using the toilet.

(C) Dressing and grooming.

(D) Feeding, including preparation and cleanup.

(3) The provision of assistance as follows:

(A) Through providing reminders or cues to take medication, the opening of pre-set medication containers, and providing assistance in the handling or ingesting of noncontrolled substance medications, including eye drops, herbs, supplements, and over-the-counter medications.

(B) To an individual who is unable to accomplish the task due to an impairment and who is:

(i) competent and has directed the services; or

(ii) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.

(Indiana State Department of Health; 410 IAC 17-9-4; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)

410 IAC 17-9-5 "Branch office" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 5. "Branch office" means a location or site from which a home health agency provides services for a portion of the total geographic area served by the parent home health agency. To be a branch office, the office must be part of the parent agency and share administration, supervision, and services with the parent agency. The parent agency and the branch office must be capable of sharing emergency functions, including services, on a daily basis. A branch office must be located within one hundred and *[sic.]* **twenty (120) minutes driving time of the parent agency.** *(Indiana State Department of Health; 410 IAC 17-9-5; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-6 "Bylaws" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 6. "Bylaws" means a written set of rules adopted by a home health agency for governing the agency's operation. *(Indiana State Department of Health; 410 IAC 17-9-6; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-7 "Clinical note" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 7. "Clinical note" means a notation written and dated by a member of the health team regarding his or her contact with a patient who is being treated under a medical plan of care. *(Indiana State Department of Health; 410 IAC 17-9-7; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-8 "Closed files" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 8. "Closed files" means those files which concern services provided prior to a patient's discharge. *(Indiana State Department of Health; 410 IAC 17-9-8; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-9 "Continuing education program" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 9. "Continuing education program means one (1) or more in-service training classes offered to home health aides for the purpose of satisfying the continuing education requirement. *(Indiana State Department of Health; 410 IAC 17-9-9; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-10 "Current service files" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 10. "Current service files" means those files concerning a patient who is currently receiving services from the home health agency. *(Indiana State Department of Health; 410 IAC 17-9-10; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-11 "Department" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 11. "Department" means the Indiana state department of health. *(Indiana State Department of Health; 410 IAC 17-9-11; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2478)*

410 IAC 17-9-12 "Encounter" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 12. "Encounter" means a direct personal contact between a patient and the person authorized by the home health agency to furnish services to the patient. *(Indiana State Department of Health; 410 IAC 17-9-12; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)*

410 IAC 17-9-13 "Frequency of visits" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 13. "Frequency of visits" means the number of encounters in a given period between a patient and the person authorized by the home health agency to furnish services to the patient. "Frequency of visits" may be expressed as a number or a range. The number of encounters must be at least one (1). *(Indiana State Department of Health; 410 IAC 17-9-13; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)*

410 IAC 17-9-14 "Governing body" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 14. "Governing body" means person or group of persons who have the legal and financial responsibility for the home health agency's overall operation. *(Indiana State Department of Health; 410 IAC 17-9-14; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)*

410 IAC 17-9-15 "Health care professional" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-10-1; IC 25-14; IC 25-22.5; IC 25-23-1; IC 25-23.5; IC 25-23.6-6-2; IC 25-24; IC 25-26-13; IC 25-27; IC 25-29; IC 25-35.6-1-2; IC 25-35.6-3

Sec. 15. "Health care professional" means any of the following:
(1) A licensed physician.
(2) A licensed dentist.
(3) A licensed chiropractor.
(4) A licensed podiatrist.
(5) A licensed optometrist.
(6) A nurse licensed under IC 25-23-1.
(7) A physical therapist licensed under IC 25-27 or a physical therapy assistant certified under IC 25-27.
(8) A speech-language pathologist or an audiologist licensed under IC 25-35.6-3.
(9) A speech-language pathology aide or an audiology aide (as defined in IC 25-35.6-1-2).
(10) An occupational therapist or an occupational therapist assistant certified under IC 25-23.5.
(11) A social worker licensed under IC 25-23.6 or a social work assistant.
(12) A pharmacist licensed under IC 25-26-13.
(Indiana State Department of Health; 410 IAC 17-9-15; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479; errata filed Mar 28, 2002, 4:28 p.m.: 25 IR 2522)

410 IAC 17-9-16 "Home health aide" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 16. "Home health aide" means an individual who provides home health aide services. The term does not include the following:
(1) A health care professional.
(2) A volunteer who provides home health aide services without compensation.
(3) An immediate member of the patient's family.
(Indiana State Department of Health; 410 IAC 17-9-16; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)

410 IAC 17-9-17 "Home health aide services" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 17. "Home health aide services" means only those home health services that may be performed by a home health aide. *(Indiana State Department of Health; 410 IAC 17-9-17; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)*

410 IAC 17-9-18 "Home health services" defined
Authority: IC 16-27-1-7
Affected: IC 12-10-17; IC 16-27-1-10; IC 25-22.5

Sec. 18. (a) "Home health services" means services that are:
(1) provided to a patient by:
(A) a home health agency; or
(B) another person under an arrangement with a home health agency;
in the temporary or permanent residence of the patient; and
(2) ordered by a licensed physician, a licensed dentist, a licensed chiropractor, a licensed podiatrist, or a licensed optometrist.

(b) The term includes the following:
(1) Nursing treatment and procedures.
(2) Physical therapy.
(3) Occupational therapy.
(4) Speech therapy.
(5) Medical social services.
(6) Home health aide services.
(7) Other therapeutic services.

(c) The term does not apply to the following:
(1) Services provided by a physician licensed under IC 25-22.5.

(2) Incidental services provided by a licensed health facility to patients of the licensed health facility.

(3) Services provided by employers or membership organizations using health care professionals for their employees, members, and families of the employees or members if the health or home care services are not the predominant purpose of the employer or a membership organization's business.

(4) Nonmedical nursing care given in accordance with the tenets and practice of a recognized church or religious denomination to a patient who depends upon healing by prayer and spiritual means alone in accordance with the tenets and practices of the patient's church or religious denomination.

(5) Services that are allowed to be performed by an attendant under IC 16-27-1-10.

(6) Authorized services provided by a personal services attendant under IC 12-10-17.

(Indiana State Department of Health; 410 IAC 17-9-18; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2479)

410 IAC 17-9-19 "Medical plan of care" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 19. "Medical plan of care" means written instructions signed by the physician, dentist, chiropractor, podiatrist, or optometrist for the provision of care or treatment to be given by a registered or practical nurse, physical or occupational therapist, speech-language pathologist, social worker, or a home health aide to a patient in the patient's place of residence. *(Indiana State Department of Health; 410 IAC 17-9-19; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-20 "Medication assistance" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 20. "Medication assistance" means the provision of assistance:

(1) through providing reminders or cues to take medication, the opening of pre-set medication containers, and providing assistance in the handling or ingesting of noncontrolled substance medications, including eye drops, herbs, supplements, and over-the-counter medications; and

(2) to an individual who is unable to accomplish the task due to an impairment and who is:

(A) competent and has directed the services; or

(B) incompetent and has the services directed by a competent individual who may consent to health care for the impaired individual.

(Indiana State Department of Health; 410 IAC 17-9-20; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)

410 IAC 17-9-21 "Member of the health team" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 21. "Member of the health team" means a health care professional or a home health aide. *(Indiana State Department of Health; 410 IAC 17-9-21; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-22 "Parent home health agency" and "parent agency" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 22. "Parent home health agency" or "parent agency" means the home health agency that develops and maintains administrative and fiscal control over branch offices. *(Indiana State Department of Health; 410 IAC 17-9-22; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-23 "Licensed practical nurse" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23

Sec. 23. "Licensed practical nurse" means a person who is licensed as a practical nurse pursuant to IC 25-23. *(Indiana State Department of Health; 410 IAC 17-9-23; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-24 "Registered nurse" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23

Sec. 24. "Registered nurse" means a nurse who is licensed as a registered nurse pursuant to IC 25-23. *(Indiana State Department of Health; 410 IAC 17-9-24; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-25 "Social worker" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23

Sec. 25. "Social worker" means a person who has a master's degree from a school of social work accredited by the Council on Social Work Education, and who has one (1) year of social work experience in a health care setting. *(Indiana State Department of Health; 410 IAC 17-9-25; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-26 "Social work assistant" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 26. "Social work assistant" means an individual who has a baccalaureate degree in psychology, sociology, or other field related to social work, and has had at least one (1) year of social work experience in a health care setting and is supervised by a social worker. *(Indiana State Department of Health; 410 IAC 17-9-26; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-27 "Speech language pathologist" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-35.6

Sec. 27. "Speech language pathologist" means an individual who is licensed to practice speech language pathology pursuant to IC 25-35.6. *(Indiana State Department of Health; 410 IAC 17-9-27; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2480)*

410 IAC 17-9-28 "Summary report" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 28. "Summary report" means a clinical synopsis of the pertinent factors from the clinical notes regarding a patient requiring a medical plan of care, which is submitted as a report to the physician. *(Indiana State Department of Health; 410 IAC 17-9-28; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2481)*

410 IAC 17-9-29 "Supervision" defined
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 29. "Supervision" means guidance to a subordinate by a qualified health care professional for the accomplishment of a function or activity. Supervision shall be evidenced by documentation that demonstrates consistent, meaningful interaction and guidance between the qualified health care professional and his or her subordinate. *(Indiana State Department of Health; 410 IAC 17-9-29; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2481)*

SECTION 2. 410 IAC 17-10 IS ADDED TO READ AS FOLLOWS:

Rule 10. Home Health Licensure

410 IAC 17-10-1 Licensure
Authority: IC 16-27-1-7
Affected: IC 5-2-5; IC 12-17-15-3; IC 16-20; IC 16-22-8; IC 16-27-1; IC 25-22.5

Sec. 1. (a) No home health agency shall be opened, operated, managed, maintained, or otherwise conduct business without a license issued by the department.

(b) A license is required for any home health agency providing care in Indiana where the parent agency is located in a state other than Indiana. The home health agency must be authorized by the secretary of state to conduct business in Indiana and have a branch office located in Indiana.

(c) Application for a license to operate a home health agency shall be made on a form provided by the department and shall be accompanied by a nonrefundable fee of one hundred dollars ($100).

(d) Disclosure of ownership and management information must be made to the department at the time of the home health agency's initial request for licensure, for each survey, and at the time of any change in ownership or management. The disclosure must include the following:

(1) The name and address of all persons having at least five percent (5%) ownership or controlling interest in the home health agency.

(2) The name and address of each person who is an officer, a director, a managing agent, or a managing employee of the home health agency.

(3) The name and address of the corporation, association, or other company that is responsible for the management of the home health agency, and the name and address of the chief executive officer and the chairman or equivalent position of the governing body of that corporation, association, or other legal entity responsible for the management of the home health agency.

(e) After receiving a completed application, the nonrefundable fee required by subsection (c) of this rule, and disclosure of ownership and management information, the department may issue a letter of approval for operating a home health agency for a period of up to ninety (90) days pending an on-site inspection. In determining whether to issue the letter of approval, the department shall consider the following factors:

(1) Whether the department has filed an action against an agency owned or operated by the applicant that resulted in:

(A) the revocation of a license;

(B) the denial or renewal of a license;

(C) the issuance or renewal of a probationary license; or

(D) the payment of a civil penalty.

(2) Whether the department has issued an order against an agency owned or operated by the applicant.

(3) Whether an agency owned or operated by the applicant has surrendered its license to the department.

(4) Whether any injunction has been issued against an agency owned or operated by the applicant; and

(5) Whether an agency owned or operated by the applicant has operated in substantial violation of this rule or any other law governing home health agencies at any time within two (2) years immediately preceding the date that the applicant applied for a license.

(f) The department may extend this ninety (90) day period for a total of one hundred twenty (120) days in fifteen (15) day increments. Such decision to grant an extension shall take into consideration the health, safety, and welfare of the citizens the home health agency serves and the individual circumstances warranting the need for the extension. The home health agency must provide the service(s) that have been specified on the application prior to the inspection and must have a minimum of three (3) patients for record review. Record review may consist of both open and closed patient files.

(g) In determining whether to issue the initial license to

operate a home health agency, the department may consider the factors described under subsection (e) of this rule and the results of the initial survey.

(h) The license shall relate back to and reflect the date of the first day of the ninety (90) day letter issued by the department.

(i) In determining whether to renew a license to operate a home health agency, the department may consider the factors described under subsection (e) of this rule and any actions pending against the home health agency.

(j) In conducting a survey, a surveyor shall receive copies of any and all documents necessary to make a determination of compliance. The surveyor may make copies with permission of the home health agency, or supervise any copying process to ensure that photocopies are true and accurate. At the sole discretion of the department and for good cause shown, the home health agency may be granted up to twenty-four (24) hours to produce documents requested by the surveyor.

(k) A home health agency may apply to provide a service that was not listed in its application or renewal application by notifying the department in writing of the new service, the date the service is intended to be offered and all supporting documentation that shows the home health agency is qualified to provide the additional service. Such documentation includes, but is not limited to, the following:

(1) Personnel qualifications and licensing.

(2) Limited criminal history from the Indiana central repository established by IC 5-2-5.

(3) Procedures for the supervision of personnel.

(4) Contracts between the home health agency and any person offering the new service.

(5) Records of physical exams showing that personnel are free of communicable disease. In the event the initial information submitted is not sufficient for the department to determine the home health agency's compliance regarding the new service, the department will inform the home health agency of the additional documents required. A home health agency may not offer additional services until it has received approval from the department to do so.

(l) The following are not required to be licensed as a home health agency:

(1) A physician licensed under IC 25-22.5.

(2) An individual whose permanent residence is in the patient's residence or who is a member of the patient's immediate family.

(3) Incidental services provided by licensed health facilities to their patients.

(4) An employee of a person holding a license under IC 16-27-1 who provides home health services only as an employee of the licensed person.

(5) A local health department established under IC 16-20.

(6) A health care professional who provides one health service through a contract with a person licensed under IC 16-27-1.

(7) A durable medical equipment supply company that furnishes equipment but provides no home health services to persons in their homes.

(8) A drugstore or wholesale medical supply company that furnishes no home health services to persons in their home.

(9) A volunteer who provides home health aide services without compensation.

(10) An individual health care professional who provides professional services to a patient in the temporary or permanent residence of the patient.

(11) An entity does not need a home health license to provide early intervention services (as defined in IC 12-17-15-3) to a child pursuant to a state program funded by the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.).

(m) Except as provided in 410 IAC 17-11-5, each license shall be for a term of one (1) year and shall expire one (1) year from the date of issuance. The licensee shall notify the department in writing thirty (30) days in advance of closing or selling the home health agency.

(n) Each license shall be issued only for the home health agency named in the application and shall not be transferred or assigned. Upon sale, assignment, lease, or other transfer, voluntary or involuntary, including those transfers that qualify as changes of ownership, a new owner or person in interest shall obtain a license from the department prior to maintaining, operating, or conducting a home health agency.

(o) The licensee shall submit an annual activity report to the department on a form provided by the department.

(p) Surveys may be, but are not limited to, the following:

(1) Unannounced surveys conducted annually for compliance.

(2) Post survey revisits conducted based on a home health agency's plan of correction and for the purpose of determining compliance.

(3) Patient care complaints.

(Indiana State Department of Health; 410 IAC 17-10-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2481)

SECTION 3. 410 IAC 17-11 IS ADDED TO READ AS FOLLOWS:

Rule 11. State Administrative Actions

410 IAC 17-11-1 Actions by the commissioner

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. The commissioner of the department may take one (1) or more of the following actions on any ground listed in section 2 of this rule:

(1) Issue a letter of correction.

(2) Issue a probationary license.

(3) Conduct a resurvey.

(4) Deny a license or renewal of a license.

(5) Revoke a license.

(6) Impose a civil penalty in an amount not to exceed ten thousand dollars ($10,000).

(Indiana State Department of Health; 410 IAC 17-11-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2482)

410 IAC 17-11-2 Grounds for actions by the commissioner

Authority: IC 16-27-1-7
Affected: IC 4-21.5; IC 16-27-1

Sec. 2. The commissioner may take action under section 1 of this rule on any of the following grounds:

(1) Violation of any of the provisions of IC 16-27 or these rules *[this article]***.**

(2) Permitting, aiding, or abetting the commission of an illegal act in a home health agency.

(3) Conduct or practice found by the department to be detrimental to the welfare of the patients of the home health agency.

(Indiana State Department of Health; 410 IAC 17-11-2; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)

410 IAC 17-11-3 Renewal of home health licensure

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. An application for renewal of license shall be filed with the department at least sixty (60) days prior, but not sooner than ninety (90) days before, the expiration date of the current license. *(Indiana State Department of Health; 410 IAC 17-11-3; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)*

410 IAC 17-11-4 Civil penalties

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 4. (a) The commissioner may commence an action under IC 16-27-1 to levy civil penalties against a person who:

(1) fails to comply with IC 16-27 or this article; or

(2) interferes with or obstructs the department or its designated agent in the performance of duties pursuant to IC 16-27-1.

(b) A monetary civil penalty may be sought for each documented violation of IC 16-27-1 or this article. Monetary civil penalties issued may not exceed ten thousand dollars ($10,000) per violation.

(c) In determining the seriousness of the violation and the specific amount of the civil penalty to be sought for each violation, the commissioner may consider, but is not limited to, the following:

(1) The potential for harm or imminent threat to the patient's health.

(2) The extent of deviation from statutory or regulatory requirements.

(3) The degree of willfulness or negligence.

(4) The history of noncompliance.

(d) The absence of direct harm will not necessarily result in assessment of a lower penalty for a violation. *(Indiana State Department of Health; 410 IAC 17-11-4; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)*

410 IAC 17-11-5 Probationary license

Authority: IC 16-27-1-7
Affected: IC 16-27-1-12

Sec. 5. A probationary license may be issued pursuant to IC 16-27-1-12 for three (3) months. The probationary license may be reissued but not more than three (3) probationary licenses may be issued during a twelve (12) month period. The issuance of a probationary license results in the automatic expiration of any other license held under this article. *(Indiana State Department of Health; 410 IAC 17-11-5; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)*

SECTION 4. 410 IAC 17-12 IS ADDED TO READ AS FOLLOWS:

Rule 12. Home Health Administration and Management

410 IAC 17-12-1 Home health agency administration and management

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 16-27-2

Sec. 1. (a) Organization, services furnished, administrative control, and lines of authority for the delegation of responsibility down to the patient care level shall be clearly set forth in writing and be readily identifiable. Administrative and supervisory responsibilities shall not be delegated to another agency or organization, and all services not furnished directly, including services provided through a branch office, shall be monitored and controlled by the parent agency.

(b) A governing body, or designated person(s) so functioning, shall assume full legal authority and responsibility for the operation of the home health agency. The governing body shall appoint a qualified administrator, adopt and periodically review written bylaws or an acceptable equivalent, and oversee the management and fiscal affairs of the home health agency.

(c) An individual need not be a home health agency employee or be present full time at the home health agency in order to qualify as its administrator. The administrator, who may also be the supervising physician or registered nurse required by subsection (d) of this rule, shall do the following:

(1) Organize and direct the home health agency's ongoing functions.

(2) Maintain ongoing liaison among the governing body and the staff.

(3) Employ qualified personnel and ensure adequate staff education and evaluations.

(4) Ensure the accuracy of public information materials and activities.

(5) Implement a budgeting and accounting system.

(6) Ensure that the home health agency meets all rules and regulations for licensure.

(7) Upon request, make available to the commissioner or his designated agent all:

(A) reports;

(B) records;

(C) minutes;

(D) documentation;

(E) information; and

(F) files;

required to determine compliance within seventy-two (72) hours of such request or, in the event such a request is made in conjunction with a survey, by the time the surveyor exits the home health agency, whichever is sooner.

(8) Ensure that a qualified person is authorized in writing to act in the administrator's absence.

(d) A physician or a registered nurse who has two (2) years of nursing experience, with at least one (1) year of supervisory or administrative experience, shall supervise and direct nursing and other therapeutic services. Such person or similarly qualified alternate shall be on the premises or capable of being reached immediately by phone, pager, or other means. In addition, the person must be able to respond to an emergency, provide guidance to staff, answer questions, and resolve issues within a reasonable amount of time, given the emergency or issue that has been raised.

(e) The administrator shall be responsible for an ongoing quality assurance program designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, resolve identified problems, and improve patient care.

(f) Personnel practices for employees shall be supported by written policies. All employees caring for patients in Indiana shall be subject to Indiana licensure, certification, or registration required to perform the respective service. Personnel records of employees who deliver home health services shall be kept current and shall include documentation of orientation to the job, including:

(1) Receipt of job description.

(2) Qualifications.

(3) A copy of limited criminal history pursuant to IC 16-27-2.

(4) A copy of current license, certification, or registration.

(5) Annual performance evaluations.

(g) Personnel records of the supervising nurse, appointed pursuant to subsection (d) of this rule, shall be kept current and shall include a copy of the following:

(1) Limited criminal history pursuant to IC 16-27-2.

(2) Nursing license.

(3) Annual performance evaluations.

(4) Documentation of orientation to the job.

Performance evaluations required by this subsection must be performed every nine (9) to fifteen (15) months of active employment.

(h) Each employee who will have direct patient contact shall have a physical examination by a physician or nurse practitioner no more than one hundred eighty (180) days before the date that the employee has direct patient contact. The physical examination shall be of sufficient scope to ensure that the employee will not spread infectious or communicable diseases to patients.

(i) The home health agency shall require all employees who will have direct patient contact to complete a PPD (mantoux) skin test for tuberculosis no more than thirty (30) days before the date that the employee has direct patient contact and annually thereafter for negative findings. Positive findings shall require appropriate clinical follow-up before the employee has direct patient contact, but no repeat skin test. A physician shall advise and approve policies regarding positive outcomes. The home health agency shall follow the Centers for Disease Control and Prevention guidelines for administering the tuberculin skin test. These guidelines are the "Core Curriculum on Tuberculosis", Chapter IV(B), Fourth Edition (2000).

(j) The information obtained from the physical examinations required by subsection (h) of this rule and PPD (mantoux) skin tests and clinical follow-ups required by subsection (i) of this rule must be maintained in separate medical files and treated as confidential medical records, except as provided in subsection (k) of this rule.

(k) The following records shall be made available, on request, to the department for review:

(1) Personnel records and policies that document the home health agency's compliance with subsection (f) of this rule.

(2) Records of physical examinations that document the agency's compliance with subsection (h) of this rule.
(3) Records of PPD (mantoux) skin tests, the results of the skin tests, appropriate clinical follow-up for positive findings, and any other records that document the home health agency's compliance with subsection (i) of this rule.

(l) The department shall treat the information described in subsection (k) of this rule as confidential medical records and use it only for the purposes for which it was obtained.

(m) Policies and procedures shall be written and implemented for the control of communicable disease in compliance with applicable federal and state laws. *(Indiana State Department of Health; 410 IAC 17-12-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2483)*

410 IAC 17-12-2 Quality assessment and performance improvement

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 2. (a) The home health agency must develop, implement, maintain, and evaluate a quality assessment and performance improvement program. The program must reflect the complexity of the home health organization and services (including those services provided directly or under arrangement). The home health agency must take actions that result in improvements in the home health agencies performance across the spectrum of care. The home health agency's quality assessment and performance improvement program must use objective measures.

(b) The home health agency shall provide at least one (1) of the following services:
(1) Nursing treatment and procedure.
(2) Home health aide services.
(3) Physical therapy.
(4) Speech-language pathology.
(5) Occupational therapy.
(6) Social services.

(c) In all cases involving the provision of home health aide services, the home health agency shall provide case management by a health care professional acting within the scope of his or her practice. Such case management shall include an initial home visit for assessment of a patient's needs to determine the type, appropriateness, and adequacy of requested service, and the development of the patient care plan.

(d) If personnel under contracts are used by the home health agency, there shall be a written contract between those personnel and the home health agency that specifies the following:
(1) That patients are accepted for care only by the primary home health agency.
(2) The services to be furnished.
(3) The necessity to conform to all applicable home health agency policies including personnel qualifications.
(4) The responsibility for participating in developing plans of care.
(5) The manner in which services will be controlled, coordinated, and evaluated by the primary home health agency.
(6) The procedures for submitting clinical notes, scheduling of visits, and conducting periodic patient evaluation.
(7) The procedures for payment for services furnished under the contract.

(e) Services furnished under arrangements are subject to a written contract conforming with the requirements specified in subsection (d) of this rule.

(f) When contracting temporary services from another licensed home health agency, organization, or independent contractor, the personnel records shall be maintained at the office of the employer and shall be available to the home health agency upon two (2) hours' notice.

(g) All personnel providing services shall maintain effective communications to assure that their efforts appropriately complement one another and support the objectives of the patient's care. The means of communication and the results shall be documented in the clinical record or minutes of case conferences.

(h) The home health agency shall coordinate its services with other health or social service providers serving the patient.

(i) A home health agency must develop and implement a policy requiring a notice of discharge of service to the patient, the patient's legal representative, or other individual responsible for the patient's care at least five (5) calendar days before the services are stopped.

(j) The five (5) day period described in subsection (i) of this rule does not apply in the following circumstances:
(1) The health, safety, and/or welfare of the home health agency's employees would be at immediate and significant risk if the home health agency continued to provide services to the patient.
(2) The patient refuses the home health agency's services.
(3) The patient's services are no longer reimbursable based on applicable reimbursement requirements and the home health agency informs the patient of community resources to assist the patient following discharge; or
(4) The patient no longer meets applicable regulatory criteria, such as lack of physician's order, and the home health agency informs the patient of community resources to assist the patient following discharge.

(k) A home health agency must continue, in good faith, to attempt to provide services during the five (5) day period described in subsection (i) of this rule. If the home health agency cannot provide such services during that period, its continuing attempts to provide the services must be documented. *(Indiana State Department of Health; 410 IAC 17-12-2; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2485)*

410 IAC 17-12-3 Patient rights
Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 3. (a) The patient or the patient's legal representative has the right to be informed of the patient's rights through effective means of communication. The home health agency must protect and promote the exercise of these rights as follows:

(1) The home health agency shall provide the patient with a written notice of the patient's right in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment.

(2) The home health agency shall maintain documentation showing that it has complied with the requirements of this section.

(b) The patient has the right to exercise his or her rights as a patient of the home health agency as follows:

(1) The patient's family or legal representative may exercise the patient's rights as permitted by law.

(2) The patient has the right to have his or her property treated with respect.

(3) The patient has the right to voice grievances regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for property by anyone who is furnishing services on behalf of the home health agency and must not be subjected to discrimination or reprisal for doing so.

(4) The patient has the right to place a complaint with the department regarding treatment or care furnished by a home health agency.

(5) The patient has the right to be informed about the care to be furnished, and of any changes in the care to be furnished as follows:

(A) The home health agency shall advise the patient in advance of the disciplines that will furnish care, and the frequency of visits proposed to be furnished.

(B) The patient has the right to participate in the planning of the care. The home health agency shall advise the patient in advance of the right to participate in planning the care or treatment and in planning changes in the care or treatment.

(C) The home health agency shall advise the patient of any change in the plan of care, including reasonable discharge notice.

(6) The patient has the right to confidentiality of the clinical records maintained by the home health agency. The home health agency shall advise the patient of the agency's policies and procedures regarding disclosure of clinical records.

(7) The patient or patient's legal representative have the right under Indiana law to access the patient's clinical records unless certain exceptions apply. The home health agency shall advise the patient or the patient's legal representative of its policies and procedures regarding the accessibility of clinical records.

(8) The patient has the right to be free from verbal, physical, and psychological abuse and to be treated with dignity.

(c) The home health agency shall investigate complaints made by a patient or the patient's family or legal representative regarding treatment or care that is (or fails to be) furnished, or regarding the lack of respect for the patient's property by anyone furnishing services on behalf of the home health agency, and shall document both the existence of the complaint and the resolution of the complaint.

(d) The home health agency shall make available to the patient upon request, a written notice in advance of furnishing care to the patient or during the initial evaluation visit before the initiation of treatment, a listing of all individuals or other legal entities who have an ownership or control interest in the agency as defined in 42 CFR § 420.201, 42 CFR § 420.202, and 42 CFR § 420.206.

(e) The home health agency must inform and distribute written information to the patient, in advance, concerning its policies on advance directives, including a description of applicable state law. The home health agency may furnish advanced directives information to a patient at the time of the first home visit, as long as the information is furnished before care is provided. *(Indiana State Department of Health; 410 IAC 17-12-3; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2486)*

SECTION 5. 410 IAC 17-13 IS ADDED TO READ AS FOLLOWS:

Rule 13. Home Health Patient Care

410 IAC 17-13-1 Patient care
Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25

Sec. 1. (a) Patients shall be accepted for care on the basis of a reasonable expectation that the patient's health needs can be adequately met by the home health agency in the patient's place of residence. Medical care shall follow a written medical plan of care established and periodically reviewed by the physician, dentist, chiropractor, optometrist, or podiatrist as follows:

(1) The medical plan of care shall be developed in consultation with the home health agency staff and shall cover all pertinent diagnoses and include the following:

(A) Mental status.
(B) Types of services and equipment required.
(C) Frequency and duration of visits.
(D) Prognosis.
(E) Rehabilitation potential.
(F) Functional limitations.
(G) Activities permitted.
(H) Nutritional requirements.
(I) Medications and treatments.
(J) Any safety measures to protect against injury.
(K) Instructions for timely discharge or referral.
(L) Therapy modalities specifying length of treatment.
(M) Any other appropriate items.

(2) The total medical plan of care shall be reviewed by the attending physician, dentist, chiropractor, optometrist, or podiatrist, and home health agency personnel as often as the severity of the patient's condition requires, but at least once every two (2) months. The health care professional staff of the home health agency shall promptly alert the person responsible for the medical component of the patient's care to any changes that suggest a need to alter the medical plan of care. A written summary report for each patient shall be sent to the physician, dentist, chiropractor, optometrist, or podiatrist at least every two (2) months.

(b) A home health agency may accept written orders for home health services from a physician, a dentist, a chiropractor, a podiatrist, or an optometrist licensed in Indiana or in any other state. If the home health agency receives an order from a physician, dentist, chiropractor, podiatrist, or optometrist who is licensed in another state, the home health agency shall take reasonable immediate steps to determine that:

(1) the order complies with the laws of the state where the order originated; and

(2) the individual who issued the order examined the patient and is licensed to practice in that state.

(c) All orders issued by a physician, a dentist, a chiropractor, a podiatrist, or an optometrist for home health services must meet the same requirements whether the order originates in Indiana or another state. Orders issued from another state may not exceed the authority allowed under orders from the same profession in Indiana under IC 25.

(d) Home health agency personnel shall promptly notify a patient's physician or other appropriate licensed professional staff and legal representative, if any, of any significant physical or mental changes observed or reported by the patient. In the case of a medical emergency, the home health agency must know in advance which emergency system to contact. *(Indiana State Department of Health; 410 IAC 17-13-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2486)*

SECTION 6. 410 IAC 17-14 IS ADDED TO READ AS FOLLOWS:

Rule 14. Home Health Care Services

410 IAC 17-14-1 Scope of services
Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 25-23-1; IC 25-27-1; IC 25-35.6

Sec. 1. (a) The home health agency shall provide nursing services by a registered nurse or a licensed practical nurse in accordance with the medical plan of care as follows:

(1) The registered nurse shall perform nursing duties in accordance with the Indiana nurse practice act (IC 25-23). Except where services are limited to therapy only, for purposes of practice in the home health setting, the registered nurse shall do the following:
(A) Make the initial evaluation visit.
(B) Regularly reevaluate the patient's nursing needs.
(C) Initiate the plan of care and necessary revisions.
(D) Initiate appropriate preventive and rehabilitative nursing procedures.
(E) Prepare clinical notes.
(F) Coordinate services.
(G) Inform the physician and other appropriate medical personnel of changes in the patient's condition and needs, counsel the patient and family in meeting nursing and related needs, participate in in-service programs, and supervise and teach other nursing personnel.
(H) Accept and carry out physician, chiropractor, podiatrist, dentist, and optometrist orders (oral and written).
(I) Assist the physician, chiropractor, podiatrist, dentist, or optometrist in evaluating level of function.
(J) Direct the activities of the licensed practical nurse.
(K) Delegate duties and tasks to licensed practical nurses and other individuals as appropriate.

(2) The licensed practical nurse shall perform duties in accordance with the Indiana nurse practice act (IC 25-23). For purposes of practice in the home health setting, the licensed practical nurse shall do the following:
(A) Provide services in accordance with agency policies.
(B) Prepare clinical notes.
(C) Assist the physician and/or registered nurse in performing specialized procedures.
(D) Prepare equipment and materials for treatments observing aseptic technique as required.
(E) Assist the patient in learning appropriate self-care techniques.
(F) Accept and carry out physician, dentist, chiropractor, podiatrist, or optometrist orders (oral and written).
(G) Inform the physician, dentist, chiropractor, podiatrist, or optometrist of changes in the patient's condition and needs after consulting with the supervising registered nurse.

(b) Any therapy services furnished by the home health agency shall be provided by:

(1) a physical therapist or physical therapist assistant supervised by a licensed physical therapist in accordance with IC 25-27-1; or

(2) an occupational therapist or occupational therapist assistant supervised by an occupation therapist in accordance with IC 25-23.5.

(3) a speech-language pathologist or audiologist in accordance with IC 25-35.6.

(c) The appropriate therapist listed in subsection (b) of this rule shall:

(1) Make an initial evaluation visit to the patient for whom only therapy services are required.

(2) Review the plan of care as often as the severity of the patient's condition requires, but at least every two (2) months.

(3) Assist the physician, chiropractor, podiatrist, dentist, or optometrist in evaluating level of function.

(4) Help develop the plan of care (revising as necessary).

(5) Prepare clinical notes.

(6) Advise and consult with the family and other home health agency personnel.

(7) Participate in in-service programs.

(d) In carrying out the responsibilities identified in subsection (c) of this rule the therapist may:

(1) direct the activities of any therapy assistant; or

(2) delegate duties and tasks to other individuals as appropriate.

(e) Any social services furnished by the home health agency, shall be provided by a social worker, or a social work assistant under the supervision of a social worker, and in accordance with the medical plan of care. The social worker shall do the following:

(1) Assist the physician and other team members in understanding the significant social and emotional factors related to the health problems.

(2) Participate in the development of the plan of care.

(3) Prepare clinical and progress notes.

(4) Work with the family.

(5) Use appropriate community resources.

(6) Participate in discharge planning and in-service programs.

(7) Act as a consultant to other home health agency personnel.

(8) Accept and carry out physician orders for social work services.

(f) This rule does not prohibit the provision of:

(1) homemaker services, including shopping, laundry, cleaning, and seasonal chores;

(2) companion type services, including transportation, letter writing, mail reading, and escort services;

(3) assistance with cognitive tasks, including managing finances, planning activities, and making decisions;

(4) attendant care services; or

(5) any other services for which an individual license, certification, registration, or permit is not required under state law.

(g) Home health aides shall be supervised by a health care professional to ensure competent provision of care. Supervision of services must be within the scope of practice of the health care professional providing the supervision.

(h) Home health aides must receive continuing education. Such continuing education shall total at least twelve (12) hours from January 1 through December 31, inclusive, with a minimum of eight (8) hours in any eight (8) of the following subject areas:

(1) Communications skills, including the ability to read, write, and make brief and accurate oral presentations to patients, caregivers, and other home health agency staff.

(2) Observing, reporting, and documenting patient status and the care or service furnished.

(3) Reading and recording temperature, pulse, and respiration.

(4) Basic infection control procedures and universal precautions.

(5) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(6) Maintaining a clean, safe, and healthy environment.

(7) Recognizing emergencies and knowledge of emergency procedures.

(8) The physical, emotional, and developmental needs of and ways to work with the populations served by the home health agency, including the need for respect for the patient, the patient's privacy, and the patient's property.

(9) Appropriate and safe techniques in personal hygiene and grooming that include the following:

(A) Bed bath.

(B) Bath, sponge, tub, or shower.

(C) Shampoo, sink, tub, or bed.

(D) Nail and skin care.

(E) Oral hygiene.

(F) Toileting and elimination.

(10) Safe transfer techniques and ambulation.

(11) Normal range of motion and positioning.

(12) Adequate nutrition and fluid intake.

(13) Medication assistance.

(14) Any other task that the home health agency may choose to have the home health aide perform.

(i) During a home health aide's first year on the state's home health aide registry, the number of hours of training for that aide shall be a prorated portion of the usual twelve (12) and eight (8) hours.

(j) A home health aide continuing education program may be offered by any organization except a home health agency that has a probationary home health agency license.

(k) The training of home health aides pursuant to a continuing education program must be performed by or under the general supervision of a registered nurse. The home health agency shall maintain sufficient documentation to demonstrate that the continuing education requirements are met.

(l) The home health agency shall be responsible for ensuring that, prior to patient contact, the individuals who furnish home health aide services on its behalf meet the requirements of this section as follows:

(1) The home health aide shall:

(A) have successfully completed a competency evaluation program that addresses each of the subjects listed in subsection (h) of this rule; and

(B) be entered on and be in good standing on the state aide registry.

(2) The home health agency shall maintain documentation, which demonstrates that the requirements of this subsection and subsection (h) of this rule were met.

(3) If the home health agency issuing the proof of the aide's achievement of successful completion of a competency evaluation program is not the employing agency, the employing agency shall keep a copy of the competency evaluation documentation in the home health aide's employment file.

(m) The home health aide shall be assigned to a particular patient by a registered nurse (or therapist in therapy only cases). The home health aide may not be assigned to perform additional tasks not included in the original competency evaluation until he or she has successfully been evaluated as competent in that task. The home health aide must report any changes observed in the patient's conditions and needs to the supervisory nurse or therapist.

(n) A registered nurse, or therapist in therapy only cases, shall make the initial visit to the patient's residence and make a supervisory visit at least every thirty (30) days, either when the home health aide is present or absent, to observe the care, to assess relationships, and to determine whether goals are being met. *(Indiana State Department of Health; 410 IAC 17-14-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2487; errata filed Mar 28, 2002, 4:28 p.m.: 25 IR 2522)*

SECTION 7. 410 IAC 17-15 IS ADDED TO READ AS FOLLOWS:

Rule 15. Home Health Clinical Records

410 IAC 17-15-1 Clinical records

Authority: IC 16-27-1-7
Affected: IC 16-27-1; IC 16-39-7-1

Sec. 1. (a) Clinical records containing pertinent past and current findings in accordance with accepted professional standards shall be maintained for every patient as follows:

(1) The medical plan of care and appropriate identifying information.

(2) Name of the physician, dentist, chiropractor, podiatrist, or optometrist.

(3) Drug, dietary, treatment, and activity orders.

(4) Signed and dated clinical notes contributed to by all assigned personnel. Clinical notes shall be written the day service is rendered and incorporated within fourteen (14) days.

(5) Copies of summary reports sent to the person responsible for the medical component of the patient's care.

(6) A discharge summary.

(7) All entries must be legible, clear, complete, and appropriately authenticated and dated. Authentication must include signatures or a secured computer entry.

(b) Original clinical records shall be retained for the length of time as required by IC 16-39-7 after home health services are terminated by the home health agency. Policies shall provide for retention even if the home health agency discontinues operations.

(c) Clinical record information shall be safeguarded against loss or unauthorized use. Written procedures shall govern use and removal of records and conditions for release of information. Patient's written consent shall be required for release of information not authorized by law. Current service files shall be maintained at the parent or branch office from which the services are provided until the patient is discharged from service. Closed files may be stored away from the parent or branch office provided they can be returned to the office within seventy-two (72) hours. Closed files do not become current service files if the patient is readmitted to service. *(Indiana State Department of Health; 410 IAC 17-15-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2489)*

SECTION 8. 410 IAC 17-16 IS ADDED TO READ AS FOLLOWS:

Rule 16. Incorporation by Reference

410 IAC 17-16-1 Incorporation by reference

Authority: IC 16-27-1-7
Affected: IC 16-27-1

Sec. 1. Chapter IV(B) of "Core Curriculum on Tuberculosis, Fourth Edition, (2000)" is hereby incorporated by reference. Copies of this publication may be obtained by writing to Technical Information Services, Centers for Prevention Services, Centers for Disease Control, Mail Stop E06, Atlanta, Georgia 30333. Copies may also be obtained from the Indiana State Department of Health, 2 North Meridian Street, Indianapolis, Indiana 46202-3006. *(Indiana*

State Department of Health; 410 IAC 17-16-1; filed Mar 18, 2002, 3:40 p.m.: 25 IR 2489)

SECTION 9. THE FOLLOWING ARE REPEALED: 410 IAC 17-1.1; 410 IAC 17-2; 410 IAC 17-3; 410 IAC 17-4; 410 IAC 17-5; 410 IAC 17-6; 410 IAC 17-7; 410 IAC 17-8.

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TITLE 836 INDIANA EMERGENCY MEDICAL SERVICES COMMISSION

LSA Document #01-296(F)

DIGEST

Amends 836 IAC 3 concerning the certification and standards of air ambulance providers. Repeals 836 IAC 3-6-1. Effective 30 days after filing with the secretary of state.

836 IAC 3-1-1
836 IAC 3-2-1
836 IAC 3-2-2
836 IAC 3-2-3
836 IAC 3-2-4
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SECTION 1. 836 IAC 3-1-1 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-1-1 Definitions
Authority: IC 16-31-2-7
Affected: IC 16-31-3-20

Sec. 1. The following definitions apply throughout this article:

~~(1) "Air-medical crew member" means a person who is certified by the commission as a paramedic or is a registered nurse or physician with an unlimited license to practice medicine.~~

(1) "14 CFR 135 and 119" means air carriers with reference to F.A.R. 135 and 119, and holding a current F.A.A. air carrier certificate, with approved air ambulance operations-helicopter or air ambulance operation-airplane operations specifications.

(2) "Advanced life support fixed-wing ambulance service provider" means a service provider that utilizes fixed-wing aircraft to provide airport to airport transports where the patients involved require a stretcher or cot and are being transported to or from a definite care medical setting.

(3) "Advanced life support rotorcraft ambulance service provider" means a service provider that utilizes rotorcraft aircraft to respond directly to the scene of a medical emergency either as an initial first responder or as a secondary responder and are utilized to airlift critically ill or injured patients directly to or between definitive care facilities or to a point of transfer with another more appropriate form of transportation.

~~(2)~~ **(4)** "Air-medical director" means a **physician with an unlimited license to practice medicine in Indiana and who has an active role in the delivery of emergency care. The** licensed physician **shall be** within an air ambulance service who is ultimately responsible for patient care during each transport. The air-medical director is responsible for directly overseeing and assuring that appropriate aircraft, air-medical ~~crew member,~~ **personnel,** and equipment are provided for each patient transported by the air ambulances within the air-medical services as well as the performance of air-medical ~~crew members.~~ **personnel.**

(5) "Air-medical personnel" means a person who is certified by the commission as a paramedic or is a registered nurse or physician with an unlimited license to practice medicine.

(6) "Certificate" or "certification" means authorization in written form issued by the commission to a person to furnish, operate, conduct, maintain, advertise, promote, or otherwise engage in providing emergency medical services as a rotorcraft or fixed-wing ambulance service provider as part of a regular course of doing business, either paid or voluntary.

(7) "F.A.A." means the Federal Aviation Administration.

(8) "F.A.R." means the federal aviation regulations, including, but not limited to, 14 CFR.

(9) "Fixed-wing ambulance" means a propeller or jet airplane.

(10) "Flight physiology" means the physiological stress of flight encountered during air medical operations to include, but not be limited to, temperature, pressure, stresses of barometric pressure changes, hypoxia, thermal and humidity changes, gravitational forces, noise, vibration, fatigue, and volume and mass of gases.

(11) "Principal operations base" means the operator's principal base of operations where required management personnel and records are maintained.

~~(3)~~ **(12)** "Rotorcraft ambulance" means an aircraft capable of vertical takeoffs and landings with the capability of hovering.

~~(4) "Rotorcraft ambulance service provider" means a service provider that utilizes rotorcraft aircraft to respond directly to the scene of a medical emergency either as an initial first responder or as a secondary additional responder and are utilized to airlift critically ill or injured patients directly to or between definitive care facilities or to a point of transfer with another more appropriate form of transportation.~~
~~(5) "Fixed-wing ambulance" means a propeller or jet aircraft.~~
~~(6) "Fixed-wing ambulance service provider" means a service provider that utilizes fixed-wing aircraft to provide airport to airport transports where the patients involved are being transported to or from a definite care medical setting.~~
~~(7) "Certified" or "certification" means authorization in written form issued by the commission to a person to furnish, operate, conduct, maintain, advertise, or otherwise engage in providing emergency medical services as a rotorcraft or fixed-wing ambulance service provider as part of a regular course of doing business, either paid or voluntary.~~
~~(8) "ATCO" means air taxi and commercial operators, with reference to air taxi and commercial operators, operations certificate outlined in Federal Aviation Regulations, Part 135.~~
~~(9) "F.A.A." means the Federal Aviation Administration.~~
~~(10) "F.A.R." means the federal aviation regulations, including, but not limited to, the following parts:~~
~~(A) F.A.R. relative to the certification of pilots and instructors.~~
~~(B) F.A.R. relative to medical standards and certification of pilots and other F.A.A. related personnel.~~
~~(C) F.A.R. relative to general operating and flight rules.~~
~~(D) F.A.R. relative to air taxi and commercial operators of small aircraft.~~
~~(11) "A.G.L." means above ground level.~~
~~(12) "Local flying area" means an area to be determined by the emergency medical services operators in statute miles not to exceed a twenty-five (25) mile radius from the dispatch point.~~
~~(13) "Cross-country" means any area outside the local flying area previously determined by the operator.~~
~~(14) "Principal operations base" means the operator's principal base of operations where required management personnel and records are maintained.~~
~~(15) "EMS landing site" means a suitable area free of obstruction, allowing for safe operation to land and takeoff a helicopter for the purpose of EMS operation.~~
~~(16) "Flight time" means the period of time from the moment the aircraft first moves under its own power for the purpose of flight until the moment it comes to rest at the next point of landing.~~
~~(17) "Pilot rest time" means the period of time that a pilot completes the required continual uninterrupted rest in any twenty-four (24) consecutive hour period of an assignment.~~
~~(18) "Pilot assignment" means the period of time that a pilot is assigned to perform duty at the designated location.~~
~~(19) "Pilot duty time" means the period of time that the operator assigns the pilot either flight time duty or other duties.~~
~~(20) "Pilot-in-command" means a qualified pilot who is responsible for the operation of the aircraft.~~

(Indiana Emergency Medical Services Commission; 836 IAC 3-1-1; filed Oct 11, 1988, 11:05 a.m.: 12 IR 366; filed May 15, 1998, 10:25 a.m.: 21 IR 3917; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2490)

SECTION 2. 836 IAC 3-2-1 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-2-1 Air ambulances; general requirements

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31

Sec. 1. (a) Any organization providing, or seeking to provide, rotorcraft ambulance services utilizing rotorcraft aircraft is required to be certified as an advanced life support rotorcraft ambulance service provider organization by the commission. The advanced life support rotorcraft ambulance service provider organization shall be certified in accordance with this article pursuant to IC 16-31 as appropriate.

(b) Certification by the commission as an advanced life support rotorcraft ambulance service provider is not required for the following:

(1) A person who provides advanced life support while assisting the case of major catastrophe, disaster, whereby persons who are certified to provide emergency medical services or advanced life support are insufficient or are unable to cope with the situation.

(2) An agency or instrumentality of the United States as defined in 836 IAC 2-1-1(4).

(c) The provider of rotorcraft ambulance services shall ensure that the aircraft used in conjunction with the provision of advanced life support services meets the guidelines as specified in this article pursuant to IC 16-31, and is certified by the commission. Each rotorcraft ambulance service provider shall meet all applicable parts of F.A.A. regulation and shall hold a valid ~~ATCO operations~~ **14 CFR 135 air carrier** certificate **or shall have a contract with the holder of a 14 CFR 135 air carrier certificate to provide aviation services under their certificate. Either must also have current F.A.A. approved air ambulance operations specifications.**

(d) Advanced life support rotorcraft ambulance service provider organizations will have a contract with one (1) or more supervising hospitals for the following services:

(1) Continuing education.

(2) Audit and review.

(3) Medical control and direction.

(4) Provide liaison and direction for supply of medications, fluids, and other items utilized by the organization.

(5) Safety and survival programs and education.

The contract shall include a detailed description of how such services will be provided to the advanced life support rotorcraft

ambulance service provider organization. In those cases where more than one (1) hospital contracts, or seeks to contract, with an advanced life support rotorcraft ambulance service provider organization as a supervising hospital, an interhospital agreement will be provided to the commission that clearly defines the specific duties and responsibilities of each hospital to ensure medical, safety, and administrative accountability of system operation. A contract is not required when the hospital and the provider are the same organization.

(e) The advanced life support rotorcraft ambulance service provider organization will have an air-medical director provided by the advanced life support rotorcraft ambulance service provider organization, or jointly with the supervising hospital, who shall be a physician who holds a currently valid unlimited license to practice medicine **in Indiana** and has an active role in the delivery of emergency care, and has knowledge of air transport problems and ~~principles of pressure phenomena.~~ **flight physiology.** The air-medical director is responsible for providing competent medical direction and overall supervision of the medical aspects of the advanced life support rotorcraft ambulance service provider organization. The duties and responsibilities of the air-medical director include, but are not limited to, the following:

(1) Assuming all medical control and authority over any and all patients treated and transported by the rotorcraft ambulance service.

(2) Providing liaison with physicians.

(3) Assuring that the drugs, medications, supplies, and equipment are available to the advanced life support rotorcraft ambulance service provider organization.

(4) Monitoring and evaluating overall **medical** operations.

(5) Assisting in the coordination and provision of continuing education.

(6) Providing information concerning the operation of the advanced life support rotorcraft ambulance service provider organization to the commission.

(7) Providing individual consultation to the air-medical personnel.

(8) Participating on the ~~assessment~~ **medical control** committee of the supervising hospital in ~~the monthly~~ **at least quarterly** audit and review of cases treated by air-medical personnel.

(9) Attesting to the competency of ~~air crewmember(s)~~ **air-medical personnel** affiliated with the advanced life support rotorcraft ambulance service provider organization.

(10) Designating an ~~individual(s)~~ **individual or individuals** to assist in the performance of these duties.

(f) Each rotorcraft ambulance service provider will designate one (1) person to assume responsibility for in-service training. This person shall be certified as a paramedic, a registered nurse, or a licensed physician, and actively ~~provides~~ **provide** patient care during air ambulance transport.

(g) A rotorcraft ambulance service provider shall not engage in conduct or practices detrimental to the health and safety of emergency patients or to members of the general public while in the course of business or service as a rotorcraft ambulance service provider.

(h) The advanced life support rotorcraft ambulance service provider organization shall have an areawide plan to provide safety education and coordinate rotorcraft ambulance service with emergency medical services rescue, law enforcement, mutual aid back-up systems, and central dispatch when available.

(i) Each advanced life support rotorcraft ambulance service provider organization shall do the following:

(1) Maintain an adequate number of trained personnel and aircraft to provide continuous twenty-four (24) hour advanced life support services.

(2) Notify the commission in writing within thirty (30) days of a paramedic's affiliation or termination of employment, or for any reason that has prohibited a certified individual from performing the procedures required of a paramedic pursuant to 836 IAC 2.

(j) Each rotorcraft ambulance service provider shall designate one (1) person to assume the responsibilities for establishment of a safety committee consisting of the following:

(1) ~~Pilot(s).~~ **Pilot or pilots.**

~~(2) Aircrewmember(s).~~

~~(3) Hospital administrator(s).~~

~~(4) Air-medical director(s).~~

(2) Air-medical personnel.

(3) Aircraft maintenance technician or technicians.

(4) Communications personnel.

The safety committee shall meet at least ~~monthly~~ **quarterly** and may be concurrent and in conjunction with the audit/review committee. *(Indiana Emergency Medical Services Commission; 836 IAC 3-2-1; filed Oct 11, 1988, 11:05 a.m.: 12 IR 367; filed May 15, 1998, 10:25 a.m.: 21 IR 3918; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2491)*

SECTION 3. 836 IAC 3-2-2 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-2-2 Certification; application

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31; IC 34-6-2-49

Sec. 2. (a) Application for certification as an advanced life support rotorcraft ambulance service provider will be made on forms prescribed by the commission and include, but not be limited to, the following:

(1) A narrative summary of plans for providing rotorcraft ambulance services, including the following:

(A) The staffing pattern of air-medical ~~crew member~~ **personnel** and pilots.

(B) Defined area of primary and secondary response and an areawide coordination plan.

(C) Base of operations, **a description of the visual flight rules weather minimums for both cross-county and local flight, and the definition of the "local flying area" quoted from the approved F.A.A. Part 135 operations specifications.**

(D) Aircraft types and identification numbers.

(E) A listing of all personnel and their qualifications by category who will regularly serve as pilots ~~air-crewmembers,~~ and ~~other medical crewmembers~~ **air-medical personnel** on the aircraft.

(F) A copy of the patient care transport record to be utilized on each transport.

(2) Plans and methodologies to ensure that the trained personnel are provided with continuing education relative to their level of training. Continuing education on air transportation problems and ~~pressure phenomena~~ **flight physiology** shall be provided on an annual basis. Continuing education will be ~~under the direct supervision of~~ **approved by** the advanced life support rotorcraft ambulance service provider organization air-medical director with the cooperation of the supervising hospital.

(3) A listing of all on-board life support and medical communications equipment available, including a list of drugs and medications to be carried on each aircraft.

(4) When appropriate, a copy of the contract between the advanced life support rotorcraft ambulance service provider organization and the supervising ~~hospital(s).~~ **hospital or hospitals.**

(5) A copy of all treatment protocols and standing orders (if applicable) under which all nonphysician personnel operate.

(6) The insurance requirement of IC 16-31 is satisfied if the rotorcraft ambulance service provider:

(A) has in force and effect public liability insurance according to:

	Minimum Limits	
Type of Liability	Each Person	Each Occurrence
Bodily injury liability excluding passengers	$75,000	$300,000
Passenger bodily injury liability	$75,000	$75,000 times 75% of total number of passenger seats installed in the aircraft
Property damage		$100,000

(B) combined coverage of a single limit of liability for each occurrence at least equal to the required minimums stated in clause (A) for bodily injury excluding passengers, passenger bodily injury, and property damage; or

(C) is a governmental entity within the meaning of ~~IC 34-4-16.5-1.~~ **IC 34-6-2-49.**

(7) The insurance coverage specified in subdivision (6) shall be for each and every aircraft owned and/or operated by or for the rotorcraft ambulance service provider.

(b) Upon approval, an advanced life support rotorcraft ambulance service provider organization will be issued certification for the provision of advanced life support services as required in 836 IAC 2 and this article.

(c) The certificate issued pursuant to this article is valid for a period of ~~one (1) year~~ **two (2) years** from the date of issue and ~~is~~ **shall be** prominently displayed at the place of business.

(d) Application for certification renewal shall be made not less than sixty (60) days prior to the expiration date of the current certificate. Application for renewal shall be made on such forms prescribed by the commission and shall show evidence of compliance with this article as set forth for original certification. *(Indiana Emergency Medical Services Commission; 836 IAC 3-2-2; filed Oct 11, 1988, 11:05 a.m.: 12 IR 368; filed May 15, 1998, 10:25 a.m.: 21 IR 3919; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2492)*

SECTION 4. 836 IAC 3-2-3 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-2-3 Minimum specifications

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31

Sec. 3. (a) The rotorcraft ambulance performance characteristics are inherent in the type of aircraft selected by the rotorcraft ambulance service provider. The aircraft and its equipment and operations shall be in compliance with prevailing F.A.R. for the type of aircraft in question and flying conditions under which the aircraft will be operated as specified in the ~~ATCO operating~~ **14 CFR 135 air carrier** certificate of the air ambulance service provider.

(b) The aircraft shall be capable of carrying a minimum of one (1) patient on a litter in a horizontal position located so as not to obstruct the pilot's vision or interfere with the performance of any member of the flight crew or required ~~medical crew(s).~~ **air-medical personnel.**

(c) There shall exist a means of securing each litter and attached patient securely to either the floor (deck), walls (bulkhead), seats, or specific litter rack or any combination thereof which shall comply with an acceptable method using either approved data from the aircraft manufacturer or data approved by the F.A.A. If data approved by the F.A.A. is required, a **field approval or** supplemental type certificate (STC) ~~should~~ **shall** be obtained.

(d) There shall be demonstrable unobstructed vertical space at the head and thorax areas of the upper surface of a ~~litter(s)~~ **litter or litters** to allow for performance of advanced life support cardiac care.

(e) Both the head and thorax of a secured patient shall be

accessible by a minimum of two (2) ~~aircrewmembers~~ **air-medical personnel** at one (1) time.

(f) The patient compartment shall have lighting available for patient observation (a minimum of forty (40) foot-candles at the level of the patient is recommended). Lighting shall be such as to not interfere with the pilots vision and will be focused, shielded, diffused, or colored illumination.

(g) The patient compartment shall have fresh air ventilation for ~~patient and crew~~ **the** comfort **of all persons on board.**

(h) The patient compartment shall have temperature regulation to assure ~~patient and crew~~ **the** comfort **of all persons on board.**

(i) The aircraft shall have one (1) door demonstrably large enough for ease of patient litter loading and unloading in the supine position.

(j) The electrical system of the aircraft shall be capable of supporting all of the ancillary equipment without the threat of overload or systems failure.

(k) Other specialized equipment may be required to conduct certain operations. The installation of this equipment shall comply with an acceptable method using either approved data from the aircraft manufacturer or data approved by the F.A.A. If data approved by the F.A.A. is required, a **field approval or** supplemental type certificate (STC) ~~should~~ **shall** be obtained.

(l) The aircraft shall have a searchlight rated as a minimum of four hundred thousand (400,000) candlepower or greater, manipulated by the pilot with a minimum movement of ninety (90) degrees vertical and one hundred eighty (180) degrees horizontal with the capability of illuminating the proposed landing site.

(m) The aircraft shall have air to ground communication capability to allow the pilot to communicate with all of the following ground personnel:
(1) Law enforcement.
(2) Fire/rescue.
(3) Ambulances.
(4) ~~Hospital(s).~~ **Hospital or hospitals.**

(n) The aircraft shall be equipped with adequate patient restraint(s) to preclude interference with the crew or aircraft flight controls.

(o) The aircraft shall have an intercommunications system. *(Indiana Emergency Medical Services Commission; 836 IAC 3-2-3; filed Oct 11, 1988, 11:05 a.m.: 12 IR 369; filed May 15, 1998, 10:25 a.m.: 21 IR 3920; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2493)*

SECTION 5. 836 IAC 3-2-4 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-2-4 Operating procedures; flight and medical
Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 4-21.5-1

Sec. 4. (a) Each organization shall maintain accurate records concerning the emergency care provided to each patient within the state **as well as the following:**

(1) All advanced life support rotorcraft ambulance service providers shall utilize a patient care transport record.

(2) All advanced life support rotorcraft ambulance service providers shall participate in the emergency medical service system review by:

(A) collecting all data elements prescribed by the commission; and

(B) reporting that information according to the procedure and schedules prescribed by the commission.

~~(b) Data shall be maintained to record the number of runs, including the following:~~
~~(1) Cardiac.~~
~~(2) Trauma, including the following:~~
~~(A) Automobile accidents.~~
~~(B) Other.~~
~~(3) Overdose.~~
~~(4) Medical emergencies, for example, diabetic or respiratory.~~
~~(5) Miscellaneous, for example, obstetrical cases.~~
~~(6) Number defibrillated.~~
~~(7) Number requiring CPR only.~~
~~(8) Number resuscitated from cardiopulmonary arrest improved to having a palpable pulse and hospital admission.~~
~~(9) Operational difficulties, for example:~~
~~(A) safety problems;~~
~~(B) equipment problems;~~
~~(C) communication problems; or~~
~~(D) other persons on the scene.~~

~~(c)~~ **(b)** Premises will be maintained, suitable to the conduct of a rotorcraft ambulance service, with provision for adequate storage ~~hangars, padding, tie-down,~~ and/or maintenance of rotorcraft ambulances and the on-board equipment.

~~(d)~~ **(c)** Each rotorcraft ambulance service provider shall have a periodic maintenance program as outlined for each specific aircraft certified by the commission in compliance with F.A.A. guidelines and manufacturer's service recommendations (MSR) as a minimum to assure that each rotorcraft ambulance, including equipment, is maintained in good, safe working condition and that rigid sanitation conditions and procedures are in effect at all times.

~~(e)~~ **(d)** All rotorcraft ambulance service provider premises, records, hangars, padding, and tie-down facilities, and rotorcraft

ambulances will be made available for inspection by the director or the director's authorized representative at any time during regularly scheduled business hours.

~~(f) Each rotorcraft ambulance service provider shall establish procedures to ensure that visual flight rules (VFR) flights adhere to the following weather minimums:~~

~~(1) Day local flights, five hundred (500) feet and one (1) mile.~~

~~(2) Day cross-country flights, eight hundred (800) feet and two (2) miles.~~

~~(3) Night local flights, eight hundred (800) feet and two (2) miles.~~

~~(4) Night cross-country flights, one thousand (1,000) feet and three (3) miles.~~

~~(g) Rotorcraft ambulance flights conducted under instrument flying rules will be flown with strict adherence to existing F.A.R.s.~~

~~(h) Each rotorcraft ambulance service provider shall establish procedures to insure that continuous flight following is maintained and documented.~~

~~(i)~~ **(e)** A determination of noncompliance with F.A.R. may result in immediate suspension of commission certification as a rotorcraft ambulance service provider.

~~(j) Rotorcraft ambulance service providers shall provide for inspection by the director or the director's authorized representative, proof of compliance with all required F.A.A. inspection programs, at place of operation during regular business hours.~~

~~(k)~~ **(f)** Each rotorcraft ambulance service provider shall make available to the commission for inspection at place of operation during regular business hours any manual of operations required under F.A.R.

~~(l)~~ **(g)** Commission certification as a rotorcraft ambulance service provider may be terminated upon the date specified in the notice.

~~(m)~~ **(h)** Each rotorcraft ambulance service provider shall establish equipment checklist procedures to ensure the following:

(1) Electronic and mechanical equipment are in proper operating condition.

(2) Rotorcraft ambulances shall be maintained in safe operating conditions at all times.

(3) Emergency patient care equipment required for rotorcraft ambulance certification is maintained in minimum quantities either directly on board the rotorcraft ambulance or available at the time of patient transport.

~~(n)~~ **(i)** Each rotorcraft ambulance service provider shall ensure that rigid sanitation conditions and procedures are in effect at all times. The following sanitation standards apply to all rotorcraft ambulances:

(1) The interior and the equipment within the aircraft are clean and maintained in good working order at all times.

(2) Freshly laundered linens are used on all litters, and pillows and linens shall be changed after each patient is transported.

(3) When the aircraft has been utilized to transport a patient known to have a communicable disease, the aircraft shall be cleansed and all contact surfaces be ~~washed with soap and water and~~ disinfected.

~~(o)~~ **(j)** A rotorcraft ambulance service provider shall not operate a rotorcraft ambulance in Indiana if the aircraft does not meet the certification requirements of this article and does not have a certificate issued pursuant to this article; however, a rotorcraft ambulance service provider may operate, for a period not to exceed ~~thirty (30)~~ **one hundred eighty (180)** consecutive days, a noncertified rotorcraft ambulance if the noncertified rotorcraft ambulance is used to replace a certified rotorcraft ambulance that has been temporarily taken out of service ~~for repair or maintenance provided~~ **providing** the following:

(1) The replacement rotorcraft ambulance meets all certification requirements of this article.

(2) The rotorcraft ambulance service provider ~~notifies~~ **shall notify** the commission, ~~by letter delivered to the commission office, or postmarked,~~ **in writing,** within ~~fifteen (15) days~~ **seventy-two (72) hours** of the ~~date~~ **time** the replacement rotorcraft is placed in service. The ~~letter~~ **written notice** shall identify **the following:**

(A) The replacement date.

(B) The certification number of the replaced rotorcraft ambulance. ~~and~~

(C) The aircraft identification number of the replacement rotorcraft.

(D) The make and type of the replacement rotorcraft ambulance.

Upon receipt of the notification, a temporary certificate shall be issued effective the date the certified rotorcraft ambulance was replaced. Temporary certification will not exceed ~~thirty (30)~~ **one hundred eighty (180)** days, and, upon return to service, the use of the replacement rotorcraft ambulance shall cease. If the replaced rotorcraft ambulance is not returned to service within the ~~thirty (30)~~ **one hundred eighty (180)** day period, use of the replacement rotorcraft ambulance shall cease **unless certification is approved in accordance with this article.**

~~(p)~~ **(k)** After proper notice and hearing, the commission may suspend or revoke a rotorcraft ambulance service provider certificate issued under this article and/or impose a penalty of up to five hundred dollars ($500) in accordance with 836 IAC 1 and 836 IAC 2 for failure to comply and maintain compliance with, or for violation of any applicable provisions, standards, or other requirements of 836 IAC 1, 836 IAC 2, or this article pursuant to IC 4-21.5-1.

~~(q)~~ **(l)** The commission may initiate proceedings to suspend or revoke a rotorcraft ambulance service provider certificate upon its own motion, or on the verified written complaint of any interested person. All such proceedings shall be held and conducted in accordance with the provisions of IC 4-21.5-1.

~~(r)~~ **(m)** Notwithstanding this section, the commission, upon finding that the public health or safety is in imminent danger, may temporarily suspend a rotorcraft ambulance service provider certificate without hearing for a period not to exceed ~~thirty (30)~~ **ninety (90)** days upon notice to the certificate holder. Upon suspension, revocation, or termination of a certificate, the provision of such service shall cease.

~~(s)~~ **(n)** A rotorcraft ambulance service provider organization owner or lessee seeking certification of a rotorcraft ambulance may petition the commission for exemption from one (1) or more of the specifications or requirements listed in this article. The commission may approve one (1) or more of the requested exemptions and grant certification. However, the commission may restrict any ~~exemption(s)~~ **exemption or exemptions** approved under this ~~this~~ article. ~~Exemption(s)~~ **Exemptions** requested will not be approved if, in the opinion of the commission, the ~~exemption(s)~~ **exemption or exemptions** would impair the capabilities of the rotorcraft ambulance service provider to provide proper emergency patient care. *(Indiana Emergency Medical Services Commission; 836 IAC 3-2-4; filed Oct 11, 1988, 11:05 a.m.: 12 IR 370; filed May 15, 1998, 10:25 a.m.: 21 IR 3920; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2494)*

SECTION 6. 836 IAC 3-2-5 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-2-5 Staffing

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 4-21.5-1

Sec. 5. (a) Each certified rotorcraft ambulance, while transporting an emergency patient, will be staffed by no less than three (3) people ~~and~~ **that have completed air-medical oriented training as prescribed by the air-medical director. Staffing will** include the following requirements:

(1) The first person shall be a properly certified pilot ~~The pilot of the rotorcraft ambulance shall possess a minimum of a Class II F.A.A. medical certificate, certification appropriate to the class of aircraft to be piloted, a valid commercial operators certificate, and two thousand (2,000) hours of rotorcraft flight experience. The staffing pattern of pilots shall provide for a minimum of ten (10) hours of continuous, uninterrupted rest in any twenty-four (24) hour period. Additionally, the pilot shall meet or exceed the following requirements in addition to those specified by the F.A.A.:~~

~~(A) If less than one hundred (100) hours in aircraft type:~~
~~(i) factory school or equivalent (ground and flight);~~
~~(ii) fifteen (15) hours as pilot-in-command in aircraft type prior to emergency medical services missions; and~~
~~(iii) one (1) flight hour of local area orientation; or~~

~~(B) If over one hundred (100) hours in aircraft type, then:~~
~~(i) current F.A.R. Part 135 check ride; or~~
~~(ii) one (1) flight hour of local area orientation.~~

~~(C) The pilot shall participate in an orientation program covering flight and medical operations.~~

who shall complete an orientation program covering flight and air-medical operations as prescribed by the air-medical director.

(2) The second person shall be ~~an Indiana-certified~~ **currently certified, registered, or licensed as one (1) of the following:**

(A) a paramedic;

(B) a registered nurse; or

(C) a physician with a valid unlimited license to practice medicine;

~~and completed air-medical oriented training as prescribed by the air-medical director.~~ **within the state the air-ambulance is stationed and operating.**

(3) The third person shall be any appropriate personnel required to properly care for the medical needs of the patient at the discretion of the air-medical director. ~~If the aircraft routinely provides transport above two thousand (2,000) feet AGL,~~ The air-medical personnel on board the aircraft shall be trained in air transport problems and ~~principles of pressure phenomena.~~ **flight physiology.**

(b) The advanced life support rotorcraft ambulance service provider organization shall notify the commission in writing within thirty (30) days of any change in the advanced life support services provided.

(c) After proper notice and hearing, the commission may levy penalties up to five hundred dollars ($500) in accordance with 836 IAC 1-2-4 or 836 IAC 2-13-1 or suspend or revoke a certificate issued under 836 IAC 1, 836 IAC 2, and this article for failure to comply and maintain compliance with, or for violation of any applicable provisions, standards, or other requirements of 836 IAC 1, 836 IAC 2, and this article.

(d) The commission may initiate proceedings to suspend or revoke a certificate upon its own motion, or on the verified written complaint of any interested person, and all such proceedings will be held in and conducted in accordance with the provisions of IC 4-21.5-1.

(e) Notwithstanding 836 IAC 1, 836 IAC 2, or this article, the commission, upon finding that the public health or safety is in imminent danger, may temporarily suspend a certificate without a hearing for a period not to exceed thirty (30) days upon notice to the certificate holder.

(f) Upon suspension, revocation, or termination of a certificate, the provision of advanced life support services shall cease. *(Indiana Emergency Medical Services Commission; 836 IAC 3-2-5; filed Oct 11, 1988, 11:05 a.m.: 12 IR 372; filed May 15, 1998, 10:25 a.m.: 21 IR 3922; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2496)*

SECTION 7. 836 IAC 3-2-6 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-2-6 Equipment list
Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31-3-20

Sec. 6. (a) The advanced life support rotorcraft ambulance service provider organization shall ensure that the following basic life support and advanced life support equipment is carried on-board each rotorcraft ambulance at the time of dispatch:

(1) Portable suction ~~with appropriate catheters and tips~~ **apparatus,** capable of a minimum **vacuum** of three hundred (300) millimeters of mercury, **equipped with wide-bore tubing and other rigid and soft pharyngeal suction tips.**

(2) Oropharyngeal airways (adult, child, and infant sizes).

(3) Nasopharyngeal airways (small, 20-24 french; medium, 26-30 french; large, 30 french or greater).

~~(4) Pocket mask w/O_2 inlet.~~

~~(5)~~ **(4)** Bag mask ~~with reservoir (adult, child, and infant sizes).~~ **ventilation units, hand operated, one (1) unit in each of the following sizes, each equipped with clear face masks and oxygen reservoirs with oxygen tubing:**

(A) Adult.

(B) Child.

(C) Infant (mask only).

(D) Neonatal (mask only).

~~(6)~~ **(5)** Portable oxygen ~~with appropriate cannulas or mask, etc.~~ **equipment of at least three hundred (300) liters capacity (D size cylinder) with yoke, medical regulator, pressure gauge, and nondependent flowmeter.**

(6) Oxygen delivery devices shall include the following:

(A) High concentration devices, two (2) each, in adult, child, and infant sizes.

(B) Low concentration devices, two (2) in adult size.

(7) Blood pressure ~~cuffs or stethoscope~~ **manometer, one (1) each in the following cuff sizes:**

(A) Large adult.

(B) Adult.

(C) Child. ~~and infant sizes).~~

(8) Stethoscope in adult size.

~~(8) Bandages and dressings~~ **(9) Wound care supplies** to include ~~but not limited to,~~ the following:

(A) Sterile gauze pads (4 × 4).

~~(B) Nonsterile gauze pads (4 × 4).~~

~~(C) Soft roller bandage (2 inches × 4 yards).~~

~~(D) Absorbent trauma dressings.~~

~~(E)~~ **(B)** Airtight dressing.

~~(F) Sterile burn sheets (commercial or hospital prepared are acceptable).~~

(C) Adhesive tape, two (2) rolls.

~~(9)~~ **(D)** Bandage shears. ~~tape, or safety pins.~~

~~(10) Adult and pediatric anti-shock trousers.~~

~~(11)~~ **(10)** Rigid extrication collars, ~~small, medium, and large~~ **two (2) each capable of the following sizes:**

(A) Pediatric.

(B) Small.

(C) Medium.

(D) Large.

~~(12) Splints, wood, wire, ladder, plastic, or pneumatic in appropriate quantities as required.~~

~~(13)~~ **(11)** Portable defibrillator with self-contained cardiac monitor and E.C.G. strip writer **and equipped** with ~~adult and pediatric~~ **defibrillation pads or** paddles, **appropriate for both adult and pediatric defibrillation,** that will not interfere with the aircraft's electrical and radio system.

~~(14) Tracheal suction catheters.~~

~~(15)~~ **(12)** Endotracheal intubation **devices, including the following** equipment: ~~to include~~

(A) Laryngoscopes with spare batteries and bulbs. ~~for each,~~

(B) Laryngoscope blades **(adult** and **pediatric, curved and straight).**

(C) Disposable endotracheal tubes, ~~in adult, child, and infant sizes.~~ **a minimum of two (2) each, sterile packaged, in sizes 3, 4, 5, 6, 7, 8, and 9 millimeters inside diameter.**

~~(16)~~ **(13)** Medications, intravenous fluids, administration sets, syringes, and needles will be specified by the air-medical director identifying types and quantities.

(b) Additional equipment and supplies approved by the supervising hospital shall be identified by the rotorcraft ambulance service provider organization's air-medical director and reported in writing to the commission for initial certification and recertification.

~~(c) Controlled drugs shall not be left on unattended aircraft unless adequate security precautions have been taken as described in the application for advanced life support rotorcraft ambulance service provider organization and approved by the commission. A closed compartment, substantially constructed and equipped with a secure locking device, may be provided within the aircraft for storage of drugs when the aircraft is not in use or unattended.~~

~~(d)~~ **(c)** All drugs shall be supplied by the supervising hospital, or by written arrangement with a supervising hospital, on an even exchange basis. Lost, stolen, or misused drugs shall only be replaced on order of the advanced life support rotorcraft ambulance service provider organization air-medical director. **All medications and advanced life support equipment are to be supplied by order of the medical director. Accountability for distribution, storage, ownership, and security of medications is subject to applicable requirements as determined by the Indiana board of pharmacy and the drug enforcement administration.** *(Indiana Emergency Medical Services Commission; 836 IAC 3-2-6; filed Oct 11, 1988, 11:05 a.m.: 12*

IR 373; filed May 15, 1998, 10:25 a.m.: 21 IR 3923; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2497)

SECTION 8. 836 IAC 3-2-7 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-2-7 Communications systems requirements
Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31-3-20

Sec. 7. (a) Each rotorcraft ambulance shall have all communications equipment required under ~~F.A.R. Part~~ **14 CFR** 135 for the type of aircraft and service provided. In addition the rotorcraft ambulance shall have radio communications equipment that allows it to communicate directly with Indiana hospitals utilizing either the Indiana hospital emergency radio network (IHERN) system or the ultrahigh frequency medical communications channels used for advanced life support.

(b) Transmitters are to operate with an output power not to exceed ten (10) watts as applicable to FCC rules and regulations.

(c) The rotorcraft ambulance service provider shall maintain a dispatch and tactical communications system with the capability to provide a coordinated voice communications linkage within the ~~defined local~~ flying area of the rotorcraft ambulance service provider. These channel(s) will be used exclusively for dispatch and tactical communications and shall be apart from any involved in the IHERN.

(d) Authorization(s) for the use of any frequencies necessary for the required communications linkages with ground personnel identified in section 3(m) of this rule shall be part of the areawide coordinated plan identified in section 2(a)(1)(B) of this rule. *(Indiana Emergency Medical Services Commission; 836 IAC 3-2-7; filed Oct 11, 1988, 11:05 a.m.: 12 IR 373; filed May 15, 1998, 10:25 a.m.: 21 IR 3923; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2498)*

SECTION 9. 836 IAC 3-2-8 IS ADDED TO READ AS FOLLOWS:

836 IAC 3-2-8 Penalties
Authority: IC 16-31-3-14
Affected: IC 4-21.5-3; IC 16-31-2-7; IC 16-31-2-9; IC 16-31-3-17; IC 16-31-10-1

Sec. 8. (a) The commission or director may penalize an ambulance service provider, or a person certified under this article, up to five hundred dollars ($500) per occurrence for a violation of patient care standards, protocols, operating procedures, or rules established by the commission.

(b) A penalty may be imposed only after a hearing or the imposition of a penalty resulting from a hearing has been held by the commission, director, or the director's designee pursuant to IC 4-21.5-3.

(c) As used in this section, "per occurrence" means a violation of patient care standards, protocols, operating procedures, or rules established by the commission that remains uncorrected for each twenty-four (24) hour period after identification by the director or the director's designee.

(d) The director or commission may assess penalties up to five hundred dollars ($500) per occurrence for the following violations:
(1) Air ambulance specifications.
(2) Emergency care equipment.
(3) Operating procedures.
(4) Patient care standards or protocols.
(5) Training requirements.
(6) Individual certification requirements.
(7) Failure to comply with this title.
(Indiana Emergency Medical Services Commission; 836 IAC 3-2-8; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2498)

SECTION 10. 836 IAC 3-3-1 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-3-1 Air ambulances; general requirements
Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31-3-20

Sec. 1. (a) Any organization **based in Indiana** providing, or seeking to provide, fixed-wing air ambulance services utilizing fixed-wing aircraft is required to be certified as an advanced life support fixed-wing air ambulance service provider organization by the commission. The advanced life support fixed-wing air ambulance service provider organization shall be certified in accordance with this article pursuant to IC 16-31 as appropriate.

(b) Certification by the commission as an advanced life support fixed-wing air ambulance service provider is not required for the following:
(1) A person who provides advanced life support while assisting the case of major catastrophe or disaster, whereby persons who are certified to provide emergency medical services or advanced life support are insufficient or are unable to cope with the situation.
(2) An agency or instrumentality of the United States as defined in 836 IAC 2-1-1(d).

(c) The provider of fixed-wing air ambulance services shall ensure that the aircraft used in conjunction with the provision of advanced life support services meets the guidelines as specified in this article pursuant to IC 16-31 and is certified by the commission. Each fixed-wing air ambulance service provider shall meet all applicable parts of F.A.A. regulation and shall hold a valid ~~ATCO operations~~ **14 CFR 135 air carrier** certificate **or shall have a contract with the holder of a 14 CFR 135 air carrier certificate to provide aviation services**

under their certificate. Either must also have current F.A.A. approved air ambulance operations specifications.

(d) Advanced life support fixed-wing air ambulance service provider organizations will have a contract with one (1) or more supervising hospitals for the following services:

(1) Continuing education.

(2) Audit and review.

(3) Medical control and direction.

(4) Provide liaison and direction for supply of medications, fluids, and other items utilized by the organization.

(5) Safety and survival programs and education.

The contract will include a detailed description of how such services will be provided to the advanced life support fixed-wing air ambulance service provider organization. In those cases where more than one (1) hospital contracts, or seeks to contract, with an advanced life support fixed-wing air ambulance service provider organization as a supervising hospital, an interhospital agreement will be provided to the commission that clearly defines the specific duties and responsibilities of each hospital to ensure medical, safety, and administrative accountability of system operation. A contract is not required when the hospital and the provider are the same organization.

(e) The advanced life support fixed-wing air ambulance service provider organization will have an air-medical director provided by the advanced life support fixed-wing air ambulance service provider organization, or jointly with the supervising hospital, who shall be a physician who holds a currently valid unlimited license to practice medicine and has an active role in the delivery of emergency care, and has knowledge of air transport problems and ~~principles of pressure phenomena.~~ **flight physiology.** The air-medical director is responsible for providing competent medical direction and overall supervision of the medical aspects of the advanced life support fixed-wing air ambulance service provider organization. The duties and responsibilities of the air-medical director include, but are not limited to, the following:

(1) Assume all medical control and authority over any and all patients treated and transported by the fixed-wing air ambulance service.

(2) Providing liaison with physicians.

(3) Assuring that the drugs, medications, supplies, and equipment are available to the advanced life support fixed-wing air ambulance service provider organization.

(4) Monitoring and evaluating overall operations.

(5) Assisting in the coordination and provision of continuing education.

(6) Providing information concerning the operation of the advanced life support fixed-wing air ambulance service provider organization to the commission.

(7) Providing individual consultation to the air-medical personnel.

(8) Participating on the assessment committee of the supervising hospital in ~~the monthly~~ **at least quarterly** audit and review of cases treated by air-medical personnel.

(9) Attesting to the competency of air ~~crewmember(s)~~ **crewmembers** affiliated with the advanced life support fixed-wing air ambulance service provider organization.

(10) Designating an ~~individual(s)~~ **individual or individuals** to assist in the performance of these duties.

(f) Each fixed-wing air ambulance service provider shall designate one (1) person to assume responsibility for in-service training. This person shall be certified as a paramedic, a registered nurse, or a licensed physician, and actively ~~provides~~ **provide** patient care during air transport.

(g) A fixed-wing air ambulance service provider shall not engage in conduct or practices detrimental to the health and safety of emergency patients or to members of the general public while in the course of business or service as a fixed-wing air ambulance service provider.

(h) Each advanced life support fixed-wing air ambulance service provider organization shall do the following:

(1) Maintain an adequate number of trained personnel and aircraft to provide advanced life support services as ~~advertized~~ **advertised** and specified in the fixed-wing air ambulance service provider's application for certification or certification renewal.

(2) Notify the commission in writing within thirty (30) days of a paramedic's affiliation or termination of employment or for any reason that has prohibited a certified individual from performing the procedures required of a paramedic pursuant to 836 IAC 2.

(i) Each fixed-wing air ambulance service provider shall designate one (1) person to assume the responsibilities for establishment of a safety committee consisting of the following:

(1) ~~Pilot(s).~~ **Pilot or pilots.**

~~(2) Aircrewmember(s).~~

~~(3) Hospital administrator(s).~~

~~(4) Air-medical director(s).~~

(2) Air-medical personnel.

(3) Aircraft maintenance technician or technicians.

(4) Communications personnel.

The safety committee shall meet at least ~~monthly~~ **quarterly** and may be concurrent and in conjunction with the audit/review committee. *(Indiana Emergency Medical Services Commission; 836 IAC 3-3-1; filed Oct 11, 1988, 11:05 a.m.: 12 IR 374; filed May 15, 1998, 10:25 a.m.: 21 IR 3924; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2498)*

SECTION 11. 836 IAC 3-3-2 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-3-2 Certification; application

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31; IC 34-6-2-49

Sec. 2. (a) Application for certification as an advanced life support fixed-wing air ambulance service provider will be made

on forms prescribed by the commission and include, but not be limited to, the following:

(1) A narrative summary of plans for providing fixed-wing air ambulance services, including the following:

(A) The staffing pattern of air-medical ~~crew member~~ **personnel** and pilots.

(B) Base of operations.

(C) Aircraft types and identification numbers.

(D) A listing of all personnel and their qualifications by category who will regularly serve as pilots ~~aircrewmembers,~~ and ~~other medical crewmembers~~ **air-medical personnel** on the aircraft.

(E) A description of the weather minimums for both cross-country and local flights.

(F) A copy of the patient care transport record to be utilized on each transport.

(2) Plans and methodologies to ensure that the trained personnel are provided with continuing education relative to their level of training. Continuing education on air transportation problems and ~~pressure phenomena~~ **flight physiology** shall be provided on an annual basis. Continuing education will be ~~under the direct supervision of~~ **approved by** the advanced life support fixed-wing air ambulance service provider organization air-medical director with the cooperation of the supervising hospital.

(3) A listing of all on-board life support and medical communications equipment available, including a list of drugs and medications to be carried on each aircraft.

(4) When appropriate, a copy of the contract between the advanced life support fixed-wing air ambulance service provider organization and the supervising ~~hospital(s).~~ **hospital or hospitals.**

(5) A copy of all treatment protocols and standing orders (if applicable) under which all nonphysician personnel will operate.

(6) The insurance requirement of IC 16-31 is satisfied if the fixed-wing air ambulance service provider:

(A) has in force and effect public liability insurance according to:

	Minimum Limits	
Type of Liability	Each Person	Each Occurrence
Bodily injury liability excluding passengers	$75,000	$300,000
Passenger bodily injury liability	$75,000	$75,000 times 75% of total number of passenger seats installed in the aircraft
Property damage		$100,000

(B) combined coverage of a single limit of liability for each occurrence, at least equal to the required minimums stated in clause (A) for bodily injury excluding passengers, passenger bodily injury, and property damage; or

(C) is a governmental entity within the meaning of ~~IC 34-4-16.5-1.~~ **IC 34-6-2-49.**

(7) The insurance coverage specified in subdivision (6) shall be for each and every aircraft owned and/or operated by or for the fixed-wing air ambulance service provider.

(b) Upon approval, an advanced life support fixed-wing air ambulance service provider organization will be issued certification for the provision of advanced life support services as required in 836 IAC 2 and this article.

(c) The certificate issued pursuant to these rules and regulations this article is valid for a period of ~~one (1) year~~ **two (2) years** from the date of issue and is prominently displayed at the place of business.

(d) Application for certification renewal shall be made not less than sixty (60) days prior to the expiration date of the current certificate. Application for renewal shall be made on such forms prescribed by the commission and shall show evidence of compliance with ~~these rules and regulations~~ this article as set forth for original certification. *(Indiana Emergency Medical Services Commission; 836 IAC 3-3-2; filed Oct 11, 1988, 11:05 a.m.: 12 IR 375; filed May 15, 1998, 10:25 a.m.: 21 IR 3925; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2499)*

SECTION 12. 836 IAC 3-3-3 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-3-3 Minimum specifications

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31-3-20

Sec. 3. (a) The fixed-wing ambulance performance characteristics are inherent in the type of aircraft selected by the fixed-wing air ambulance service provider. The aircraft and its equipment and operations shall be in compliance with prevailing F.A.R. for the type of aircraft in question and flying conditions under which the aircraft will be operated as specified in the ~~ATCO operating~~ **14 CFR 135 air carrier** certificate of the fixed-wing air ambulance service provider.

(b) The aircraft shall be capable of carrying a minimum of one (1) patient on a litter in a horizontal position located so as not to obstruct the pilot's vision or interfere with the performance of any member of the flight crew **or required air-medical personnel.**

(c) There shall exist a means of securing each litter and attached patient securely to either the floor (deck), walls (bulkhead), seats, or specific litter rack or any combination thereof which shall comply with an acceptable method using either approved data from the aircraft manufacturer or data approved by the F.A.A. If data approved by the F.A.A. is required, a **field approval or** supplemental type certificate (STC) ~~should~~ **shall** be obtained.

(d) There shall be demonstrable unobstructed vertical space

at the head and thorax areas of the upper surface of a ~~litter(s)~~ **litter or litters** to allow for performance of advanced life support cardiac care.

(e) Both the head and thorax of the secured patient shall be accessible by a minimum of two (2) ~~aircrewmembers~~ **air-medical personnel** at one (1) time.

(f) The patient compartment shall have lighting available for patient observation (a minimum of forty (40) foot-candles at the level of the patient is recommended). Lighting shall be such as to not interfere with the pilots vision and will be focused, shielded, diffused, or colored illumination.

(g) The patient compartment shall have fresh air ventilation for ~~patient and crew~~ **the** comfort **of all persons on board.**

(h) The patient compartment shall have temperature regulation to assure ~~patient and crew~~ **the** comfort **of all persons on board.**

(i) The aircraft shall have one (1) door demonstrably large enough for ease of litter patient loading and unloading in the supine position.

(j) The electrical system of the aircraft shall be capable of supporting all of the ancillary equipment without the threat of overload or systems failure.

(k) Other specialized equipment may be required to conduct certain operations. The installation of this equipment shall comply with an acceptable method using either approved data from the aircraft manufacturer or data approved by the F.A.A. If data approved by the F.A.A. is required, a **field approval or** supplemental type certificate (STC) ~~should~~ **shall** be obtained.

(l) The aircraft shall be equipped with adequate patient ~~restraint(s)~~ **restraints** to preclude interference with the crew or aircraft flight controls.

(m) The aircraft shall have an intercommunications system. *(Indiana Emergency Medical Services Commission; 836 IAC 3-3-3; filed Oct 11, 1988, 11:05 a.m.: 12 IR 376; filed May 15, 1998, 10:25 a.m.: 21 IR 3926; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2500)*

SECTION 13. 836 IAC 3-3-4 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-3-4 Operating procedures; flight and medical

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 4-21.5-1

Sec. 4. (a) Each organization shall maintain accurate records concerning the emergency care provided to each patient within the state **as well as the following:**

(1) All advanced life support fixed-wing ambulance service providers shall utilize a patient care transport record.

(2) All advanced life support fixed-wing ambulance providers shall participate in the emergency medical service system review by:

(A) collecting all data elements prescribed by the commission; and

(B) reporting that information according to the procedures and schedules prescribed by the commission.

~~(b) Data shall be maintained to record the number of runs, including the following:~~

~~(1) Cardiac.~~

~~(2) Trauma, including the following:~~

~~(A) Automobile accidents.~~

~~(B) Other.~~

~~(3) Overdose.~~

~~(4) Medical emergencies, for example, diabetic or respiratory.~~

~~(5) Miscellaneous, for example, obstetrical cases.~~

~~(6) Number defibrillated.~~

~~(7) Number requiring CPR only.~~

~~(8) Number resuscitated from cardiopulmonary arrest improved to having a palpable pulse and hospital admission.~~

~~(9) Operational difficulties, for example:~~

~~(A) safety problems;~~

~~(B) equipment problems;~~

~~(C) communication problems; or~~

~~(D) other persons on the scene.~~

~~(c)~~ **(b)** Premises shall be maintained, suitable to the conduct of a fixed-wing air ambulance service, with provision for adequate storage ~~hangars, padding, tie-down,~~ and/or maintenance of fixed-wing ambulances and the on-board equipment.

~~(d)~~ **(c)** Each fixed-wing air ambulance service provider shall have a periodic maintenance program as outlined for each specific aircraft certified by the commission in compliance with F.A.A. and manufacturer's service recommendations (MSR) guidelines as a minimum to assure that each fixed-wing ambulance, including equipment, is maintained in good, safe working condition. ~~and that rigid sanitation conditions and procedures are in effect at all times.~~

~~(e)~~ **(d)** All fixed-wing air ambulance service provider premises, records, ~~hangars, padding, and tie-down facilities,~~ and fixed-wing ambulances shall be made available for inspection by the director or his authorized representative at any time during regularly scheduled business hours.

~~(f) Each fixed-wing air ambulance service provider shall establish procedures and equipment to ensure that flights adhere to the F.A.A rules for visual flying rules and instrument flying rules weather minimums.~~

~~(g) Each fixed-wing air ambulance service provider shall comply with all F.A.R. required.~~

~~(h)~~ **(e)** A determination of noncompliance with F.A.R. may result in immediate suspension of commission certification as a fixed-wing air ambulance service provider.

~~(i) Fixed-wing air ambulance service providers shall provide for inspection by the director or the director's authorized representative, proof of compliance with all required F.A.A. inspection programs, at place of operation during regular business hours.~~

~~(j)~~ **(f)** Each fixed-wing air ambulance service provider shall make available to the commission for inspection at place of operation during regular business hours any manual of operations required under F.A.R.

~~(k)~~ **(g)** Commission certification as a fixed-wing air ambulance service provider may be terminated upon the date specified in the notice.

~~(l)~~ **(h)** Each fixed-wing air ambulance service provider shall establish equipment checklist procedures to ensure the following:

(1) Electronic and mechanical equipment are in proper operating condition.

(2) Fixed-wing ambulances shall be maintained in safe operating conditions at all times.

(3) Emergency patient care equipment required for fixed-wing ambulance certification is maintained in minimum quantities either directly on board the fixed-wing ambulance or available at the time of patient transport.

~~(m)~~ **(i)** Each fixed-wing air ambulance service provider shall ensure that rigid sanitation conditions and procedures are in effect at all times. The following sanitation standards apply to all fixed-wing ambulances:

(1) The interior and the equipment within the aircraft are clean and maintained in good working order at all times.

(2) Freshly laundered linens are used on all litters, and pillows and linens shall be changed after each patient is transported.

(3) When an aircraft has been utilized to transport a patient known to have a communicable disease, the aircraft shall be cleansed and all contact surfaces be washed with soap and water and disinfected.

~~(n)~~ **(j)** A fixed-wing air ambulance service provider shall not operate a fixed-wing ambulance in Indiana if the fixed-wing ambulance does not meet the certification requirements of this article and does not have a certificate issued pursuant to this article; however, a fixed-wing air ambulance service provider may operate, for a period not to exceed ~~thirty (30)~~ **one hundred eighty (180)** consecutive days, a ~~noncertified~~ **temporary replacement** fixed-wing ambulance if the ~~noncertified~~ **temporary replacement** fixed-wing ambulance is used to replace a certified fixed-wing ambulance that has been temporarily taken out of service ~~for repair or maintenance, provided~~ **providing** the following:

(1) The replacement fixed-wing ambulance shall meet all certification requirements of this article.

(2) The fixed-wing air ambulance service provider ~~notifies~~ **shall notify** the commission, ~~by letter delivered to the commission office, or postmarked,~~ **in writing,** within ~~fifteen (15) days~~ **seventy-two (72) hours** of the ~~date~~ **time** the replacement fixed-wing ambulance is placed in service. The ~~letter~~ **written notice** shall identify **the following:**

(A) The replacement date.

(B) The certification number of the replaced fixed-wing ambulance. ~~and~~

(C) The aircraft identification number of the replacement fixed-wing ambulance.

(D) The make and type of the replacement fixed-wing ambulance.

Upon receipt of the notification, a temporary certificate shall be issued effective the date the certified rotorcraft ambulance was replaced. Temporary certification will not exceed ~~thirty (30)~~ **one hundred eighty (180)** days, and, upon return to service, the use of the replacement fixed-wing ambulance shall cease. If the replaced fixed-wing ambulance is not returned to service within the ~~thirty (30)~~ **one hundred eighty (180)** day period, use of the replacement fixed-wing ambulance shall cease **unless certification is approved in accordance with this article.**

~~(o)~~ **(k)** After proper notice and hearing, the commission may suspend or revoke a fixed-wing air ambulance service provider certificate issued under this article and/or impose a penalty of up to five hundred dollars ($500) in accordance with 836 IAC 1 and 836 IAC 2 for failure to comply and maintain compliance with, or for violation of any applicable provisions, standards, or other requirements of 836 IAC 1, 836 IAC 2, or this article pursuant to IC 4-21.5-1.

~~(p)~~ **(l)** The commission may initiate proceedings to suspend or revoke a fixed-wing air ambulance service provider certificate upon its own motion or on the verified written complaint of any interested person. All such proceedings shall be held and conducted in accordance with the provisions of IC 4-21.5-1.

~~(q)~~ **(m)** Notwithstanding this section, the commission, upon finding that the public health or safety is in imminent danger, may temporarily suspend a fixed-wing air ambulance service provider certificate without hearing for a period not to exceed ~~thirty (30)~~ **ninety (90)** days upon notice to the certificate holder. Upon suspension, revocation, or termination of a certificate, the provision of such service shall cease.

~~(r)~~ **(n)** A fixed-wing air ambulance service provider owner or lessee seeking certification of a fixed-wing ambulance may petition the commission for exemption from one (1) or more of the specifications or requirements listed in this article. The commission may approve one (1) or more of the requested exemptions and grant certification. However, the commission

may restrict any ~~exemption(s)~~ **exemption or exemptions** approved under this ~~rule (836 IAC 3).~~ ~~Exemption(s)~~ **article. Exemptions** requested will not be approved if, in the opinion of the commission, the ~~exemption(s)~~ **exemption or exemptions** would impair the capabilities of the fixed-wing air ambulance service provider to provide proper patient care. *(Indiana Emergency Medical Services Commission; 836 IAC 3-3-4; filed Oct 11, 1988, 11:05 a.m.: 12 IR 376; filed May 15, 1998, 10:25 a.m.: 21 IR 3926; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2501)*

SECTION 14. 836 IAC 3-3-5 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-3-5 Staffing

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 4-21.5-1; IC 16-31-3-14

Sec. 5. (a) Each certified fixed-wing ambulance while transporting an emergency patient shall be staffed by no less than ~~two (2)~~ **three (3)** people and include the following requirements:

(1) The first person shall be a properly certified pilot ~~The pilot of the fixed-wing air ambulance shall possess a minimum of a Class II F.A.A. medical certificate, certification appropriate to the class of aircraft to be piloted, and a valid commercial operators certificate. The staffing pattern of pilots shall provide for a minimum of ten (10) hours of continuous uninterrupted rest in any twenty-four (24) hour period. Additionally, the pilot shall meet or exceed the following requirements in addition to those specified by the F.A.A.:~~

~~(A) If less than one hundred (100) hours is aircraft type:~~

~~(i) factory school or equivalent (ground and flight); and~~

~~(ii) fifteen (15) hours as pilot-in-command in aircraft type prior to EMS missions.~~

~~(B) If over one hundred (100) hours in aircraft type, then current F.A.R. Part 135 check ride.~~

who shall complete an orientation program covering flight, and air-medical operations as prescribed by the air-medical director.

(2) The second person shall be an Indiana certified paramedic or registered nurse or a physician with a valid unlimited license to practice medicine.

(3) ~~At~~ The ~~discretion of the air-medical director, a~~ third person **shall be any appropriate personnel** to properly care for the medical needs of the patient ~~may be~~ **as** required on board the fixed-wing aircraft in the patient compartment. ~~If the aircraft routinely provides transport above two thousand (2,000) feet AGL, the medical personnel on board the aircraft shall be trained in air transport problems and principles of pressure phenomena.~~

(4) All medical personnel on board the aircraft must be trained in air transport problems and principles of flight physiology.

(b) The advanced life support fixed-wing air ambulance service provider organization shall notify the commission in writing within thirty (30) days of any change in the advanced life support services provided.

(c) After proper notice and hearing, the commission may levy penalties up to five hundred dollars ($500) in accordance with 836 IAC 1-2-4 or 836 IAC 2-13-1 or suspend or revoke a certificate issued under 836 IAC 1, 836 IAC 2, and this article for failure to comply and maintain compliance with, or for violation of any applicable provisions, standards, or other requirements of 836 IAC 1 and 836 IAC 2.

(d) The commission may initiate proceedings to suspend or revoke a certificate upon its own motion or on the verified written complaint of any interested person, and all such proceedings will be held in and conducted in accordance with the provisions of IC 4-21.5-1.

(e) Notwithstanding 836 IAC 1 and 836 IAC 2, the commission, upon finding that the public health or safety is in imminent danger, may temporarily suspend a certificate without a hearing for a period not to exceed thirty (30) days upon notice to the certificate holder.

(f) Upon suspension, revocation, or termination of a certificate, the provision of advanced life support services shall cease. *(Indiana Emergency Medical Services Commission; 836 IAC 3-3-5; filed Oct 11, 1988, 11:05 a.m.: 12 IR 378; filed May 15, 1998, 10:25 a.m.: 21 IR 3928; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2503)*

SECTION 15. 836 IAC 3-3-6 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-3-6 Equipment list

Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31-3-20

Sec. 6. (a) The advanced life support fixed-wing air ambulance service provider organization shall ensure that the following basic life support and advanced life support equipment is available on-board each aircraft and is appropriate for the age and medical condition of the patient to be transported, at the time of transport:

(1) Portable **or fixed** suction ~~with appropriate catheters and tips~~ **apparatus,** capable of a minimum **vacuum** of three hundred (300) millimeters of mercury, **equipped with wide-bore tubing and other rigid and soft pharyngeal suction tips.**

(2) Oropharyngeal airways **(adult, child, and infant sizes).**

(3) Nasopharyngeal airways **(small, 20-24 french; medium, 26-30 french; large, 30 french or greater).**

~~(4) Pocket mask w/O_2 inlet.~~

~~(5)~~ **(4)** Bag mask ~~with reservoir.~~ **ventilation units, hand operated, one (1) unit in each of the following sizes, each equipped with clear face masks and oxygen reservoirs with oxygen tubing:**

(A) Adult.
(B) Child.
(C) Infant (mask only).
(D) Neonatal (mask only).

~~(6)~~ **(5)** Portable oxygen **equipment** with ~~appropriate cannulas or mask.~~ **of at least three hundred (300) liters capacity (D size cylinder) with yoke, medical regulator, pressure gauge, and nondependent flowmeter.**

(6) Oxygen delivery device shall include the following:
(A) High concentration devices, two (2) each, in adult, child, and infant sizes.
(B) Low concentration devices, two (2) in adult size.

(7) Blood pressure ~~cuffs or stethoscope.~~ **manometer, one (1) each in the following cuff sizes:**
(A) Large adult.
(B) Adult.
(C) Child.

(8) Stethoscope in adult size.

~~(8) Bandages and dressings~~

(9) Wound care supplies to include ~~but not limited to,~~ the following:

(A) Sterile gauze pads (4 × 4).
~~(B) Nonsterile gauze pads (4 × 4).~~
~~(C) Soft roller bandage (2 × 4 yards).~~
~~(D) Absorbent trauma dressings.~~
~~(E)~~ **(B)** Airtight dressing.
~~(F) Sterile burn sheets (commercial or hospital prepared are acceptable).~~
~~(9)~~ **(C)** Bandage shears.
(**D) Adhesive** tape, ~~or safety pins.~~ **two (2) rolls.**

(10) Rigid extrication collars, ~~small, medium, and large (pediatric sizes are recommended).~~ **two (2) each capable of the following sizes:**
(A) Pediatric.
(B) Small.
(C) Medium.
(D) Large.

~~(11) Splints, wood, wire, ladder, plastic, or pneumatic in appropriate quantities as required.~~

~~(12) Urinal or bedpan.~~

~~(13)~~ **(11)** Portable defibrillator with self-contained cardiac monitor and E.C.G. strip writer **and equipped with defibrillation pads or paddles, appropriate for both adult and pediatric defibrillation,** that will not interfere with the aircraft's electrical and radio system. ~~(Pediatric paddles are recommended.)~~

~~(14) Tracheal suction catheters.~~

~~(15)~~ **(12)** Endotracheal intubation **devices, including the following** equipment: ~~to include~~
(A) Laryngoscopes with spare batteries and bulbs. ~~for each,~~
(B) Laryngoscope blades **(adult** and **pediatric, curved and straight).**
(C) Disposable endotracheal tubes, **a minimum of two (2) each, sterile packaged, in sizes 3, 4, 5, 6, 7, 8, and 9 millimeters inside diameter.**

~~(16)~~ **(13)** Medications, intravenous fluids, administration sets, syringes, and needles will be specified by the air-medical director identifying types and quantities.

(b) Additional equipment and supplies approved by the supervising hospital shall be identified by the fixed-wing air ambulance service provider organization air-medical director and reported in writing to the commission for initial certification and recertification.

~~(c) Controlled drugs will not be left on unattended aircraft unless adequate security precautions have been taken as described in the application for advanced life support fixed-wing air ambulance service provider organization and approved by the commission. A closed compartment, substantially constructed and equipped with a secure locking device, may be provided within the aircraft for storage of drugs when the aircraft is not in use or unattended.~~

~~(d)~~ **(c)** All drugs shall be supplied by the supervising hospital, or by written arrangement with a supervising hospital, on an even exchange basis. Lost, stolen, or misused drugs shall only be replaced on order of the advanced life support fixed-wing air ambulance service provider organization medical director. **All medications and advanced life support equipment are to be supplied by order of the medical director. Accountability for distribution, storage, ownership, and security of medications is subject to applicable requirements as determined by the Indiana board of pharmacy and the drug enforcement administration.** *(Indiana Emergency Medical Services Commission; 836 IAC 3-3-6; filed Oct 11, 1988, 11:05 a.m.: 12 IR 379; filed May 15, 1998, 10:25 a.m.: 21 IR 3929; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2503)*

SECTION 16. 836 IAC 3-3-7 IS AMENDED TO READ AS FOLLOWS:

836 IAC 3-3-7 Communications systems requirements
Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31-3-20

Sec. 7. (a) Each fixed-wing ambulance shall have all communications equipment required under ~~F.A.R. Part~~ **14 CFR** 135 for the type of aircraft and service provided. In addition, the fixed-wing ambulance shall have radio communications equipment that allows it to communicate directly with Indiana hospitals utilizing either the Indiana hospital emergency radio network (IHERN) system, the ultrahigh frequency medical communications channels used for advanced life support, or air-to-ground radio telephone.

(b) Transmitters are to operate with an output power not to exceed ten (10) watts as applicable to FCC rules and regulations.

(c) The fixed-wing air ambulance service provider shall maintain a dispatch and tactical communications system with

the capability to provide a voice communications linkage with the fixed-wing air ambulance service provider's base station. This channel will be used exclusively for dispatch and tactical communications and shall be apart from any involved in the IHERN.

(d) In addition to subsection (a), each multi-engine fixed-wing air ambulance shall be equipped with a minimum of two (2) VHF aircraft band transceivers and two (2) independently functioning audio panels, allowing each required pilot to communicate with ground resources separately. *(Indiana Emergency Medical Services Commission; 836 IAC 3-3-7; filed Oct 11, 1988, 11:05 a.m.: 12 IR 380; filed May 15, 1998, 10:25 a.m.: 21 IR 3929; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2504)*

SECTION 17. 836 IAC 3-3-8 IS ADDED TO READ AS FOLLOWS:

836 IAC 3-3-8 Penalties
Authority: IC 16-31-3-14
Affected: IC 4-21.5-3; IC 16-31-2-7; IC 16-31-2-9; IC 16-31-3-17; IC 16-31-10-1

Sec. 8. (a) The commission or director may penalize an ambulance service provider, or a person certified under this article, up to five hundred dollars ($500) per occurrence for a violation of patient care standards, protocols, operating procedures, or rules established by the commission.

(b) A penalty may be imposed only after a hearing or the imposition of a penalty resulting from a hearing has been held by the commission, director, or the director's designee pursuant to IC 4-21.5-3.

(c) As used in this section, "per occurrence" means a violation of patient care standards, protocols, operating procedures, or rules established by the commission that remains uncorrected for each twenty-four (24) hour period after identification by the director or the director's designee.

(d) The director or commission may assess penalties up to five hundred dollars ($500) per occurrence for the following violations:
(1) Air ambulance specifications.
(2) Emergency care equipment.
(3) Operating procedures.
(4) Patient care standards or protocols.
(5) Training requirements.
(6) Individual certification requirements.
(7) Failure to comply with this title.
(Indiana Emergency Medical Services Commission; 836 IAC 3-3-8; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2505)

SECTION 18. 836 IAC 3-5-1 IS AMENDED TO READ AS FOLLOWS:

Rule 5. Registry for Out-of-State Advanced Life Support Fixed-Wing Ambulance Service Provider

836 IAC 3-5-1 Certificate of registry
Authority: IC 16-31-2-7; IC 16-31-3-20
Affected: IC 16-31-3-20

Sec. 1. (a) Application for ~~certification~~ **certificate of registry** as a fixed-wing ambulance service provider shall be made on forms prescribed by the commission and include, but are not limited to, a narrative summary of plans for providing fixed-wing ambulance services, including the following:
(1) The staffing pattern of personnel.
(2) Base of operations and a level of care to be provided.
(3) The training and experience of the applicant in the transportation and care of patients.
(4) A description and general location of each aircraft to be used as an air ambulance, including the make, model, year of manufacture, insignia, name or monogram, or other distinguishing characteristics.
(5) Types and quantity of medical equipment on board.
(6) Proof of current valid certification or license issued by another state.
(7) Other information as requested by the commission.

(b) Upon approval by the commission, the fixed-wing ambulance service provider shall be ~~certified~~ **registered** by the commission. ~~and a certificate will be issued.~~

(c) Each fixed-wing ambulance shall comply with all applicable F.A.A. and F.A.R. requirements pertaining to operating as a commercial air transport service.

(d) Certificate of registry is required for all advanced life support fixed-wing ambulance service providers based outside of Indiana and transporting patients originating in Indiana. *(Indiana Emergency Medical Services Commission; 836 IAC 3-5-1; filed Oct 11, 1988, 11:05 a.m.: 12 IR 380; filed May 15, 1998, 10:25 a.m.: 21 IR 3930; filed Apr 4, 2002, 9:08 a.m.: 25 IR 2505)*

SECTION 19. 836 IAC 3-6-1 IS REPEALED.

LSA Document #01-296(F)
Notice of Intent Published: 24 IR 4016
Proposed Rule Published: November 1, 2001; 25 IR 472
Hearing Held: November 27, 2001
Approved by Attorney General: March 19, 2002
Approved by Governor: April 3, 2002
Filed with Secretary of State: April 4, 2002, 9:08 a.m.
Incorporated Documents Filed with Secretary of State: 14 CFR 119 and 14 CFR 135.

TITLE 836 INDIANA EMERGENCY MEDICAL SERVICES COMMISSION

LSA Document #01-297(F)

DIGEST

Amends 836 IAC 1 concerning the certification of ambulance service providers, including the application process, requirements for ambulances, emergency care equipment, and basic life support nontransport providers. Amends 836 IAC 2 concerning the certification process of advanced life support providers. Adds 836 IAC 4-7-3.5, 836 IAC 4-9-2.5, and 836 IAC 4-10 concerning the certification and in-service requirements for emergency medical services personnel. Effective 30 days after filing with the secretary of state.

836 IAC 1-2-1
836 IAC 1-3-5
836 IAC 1-11-1
836 IAC 1-11-2
836 IAC 1-11-3
836 IAC 2-2-1
836 IAC 2-4.1-2
836 IAC 2-7.1-1
836 IAC 4-7-3.5
836 IAC 4-9-2.5
836 IAC 4-10

SECTION 1. 836 IAC 1-2-1 IS AMENDED TO READ AS FOLLOWS:

836 IAC 1-2-1 General certification provisions

Authority: IC 16-31-2-7
Affected: IC 4-21.5; IC 16-31-3

Sec. 1. (a) A person shall not engage in the business or service of providing emergency ambulance services upon any public way of the state unless they hold a valid certificate issued by the commission for engaging in such a business or service as an ambulance service provider.

(b) A certificate is not required for a person who provides emergency ambulance service, an emergency medical technician, or an ambulance when:

(1) rendering assistance to persons certified to provide emergency ambulance service or to emergency medical technicians;

(2) operating from a location or headquarters outside Indiana to provide emergency ambulance services to patients who are picked up outside Indiana for transportation to locations within Indiana;

(3) providing emergency medical services during a major catastrophe or disaster with which persons or ambulance services are insufficient or unable to cope;

(4) an agency or instrumentality of the United States and any emergency medical technicians or ambulances of such agency or instrumentality are not required to be certified or to conform to the standards prescribed under 836 IAC 1-1-1(3); or

(5) transportation of a patient from another state into Indiana and returned.

(c) Each ambulance, while transporting a patient, shall be staffed by not less than two (2) persons, one (1) of whom shall be a certified emergency medical technician and who shall be in the patient compartment unless an exemption is approved by the commission through subsection (g).

(d) After notice and hearing, the commission may and is authorized to suspend or revoke a certificate issued under IC 16-31 or impose a fine of up to five hundred dollars ($500) in accordance with section 4 of this rule, or both, for:

(1) fraud or misrepresentation in procuring certification; **or**

(2) failure to comply and maintain compliance with, or for violation of, any applicable provisions, standards, or other requirement of IC 16-31 or this title.

The commission may initiate proceedings to suspend or revoke a certificate upon its own motion, or on the verified written complaint of any interested person, and all such proceedings shall be held and conducted in accordance with IC 4-21.5.

(e) Notwithstanding the provision of subsection (d), the commission, upon finding that the public health or safety is in imminent danger, may temporarily suspend a certificate without hearing for a period not to exceed ninety (90) days upon notice to the certificate holder.

(f) Upon suspension, revocation, or termination of a certificate, the provision of such service shall cease.

(g) An ambulance service provider seeking certification of a land ambulance specially staffed, equipped, or uniquely designed to provide interhospital emergency transportation of critical care patients, for example:

(1) coronary care;
(2) high risk infant;
(3) poisoning;
(4) psychiatric; and
(5) alcohol and drug overdose;

may petition the commission for exemption from one (1) or more of the specifications or requirements listed in this article. The ambulance service provider shall submit with the application a description of the medical capability of each person who usually staffs the patient compartment when transporting an emergency patient and a description of radio communications capabilities. The commission may approve one (1) or more of the requested exemptions and grant certification. However, the commission may restrict any exemption(s) approved under this article. Exemption(s) requested shall not be approved if, in the opinion of the commission, the exemption(s) would impair the capabilities of the ambulance service provider to provide proper emergency patient care.

(h) An ambulance service provider seeking certification for other than a land or air ambulance may petition the commission for any exemptions from one (1) or more of the requirements set forth in this article and 836 IAC 2.

(i) Each emergency patient shall be transported in a certified ambulance.

(j) Notify the commission in writing within thirty (30) days of any changes in items listed in section 2(a) of this rule.

(k) Notify the commission in writing immediately of change in medical director, including medical director approval form and protocols.

(l) Each ambulance service provider shall secure a medical director who shall be a physician with an unlimited license to practice medicine in Indiana and who has an active role in the delivery of emergency care. The duties and responsibilities of the medical director are as follows:

(1) Provide liaison between the local medical community and the emergency medical service provider.

(2) Assure compliance with defibrillation training standards and curriculum established by the commission.

(3) Monitor and evaluate the day-to-day medical operations of the emergency medical service organization.

(4) Assist in the continuing education programs of the emergency medical service organization.

(5) Provide technical assistance concerning the delivery of automated defibrillation and other medical issues.

(6) Provide individual consultation to the emergency medical personnel affiliated with the emergency medical service organization.

(7) Participate in the audit and review of cases treated by the emergency medical personnel of the emergency medical service organization.

(8) Assure compliance with approved medical standards established by the commission performed by organization.

(9) Establish protocols for automatic defibrillation, airway management, ~~wound care,~~ ~~patient stabilization,~~ patient-assisted medications, and emergency medical technician-administered medications as approved by the commission.

(Indiana Emergency Medical Services Commission; Emergency Medical Services Rule I, A; filed Jun 5, 1975, 11:57 a.m.: Rules and Regs. 1976, p. 84; filed Dec 15, 1977: Rules and Regs. 1978, p. 244; filed Dec 15, 1977: Rules and Regs. 1978, p. 245; filed Nov 3, 1980, 3:55 p.m.: 3 IR 2192; errata, 4 IR 531; filed Oct 13, 1981, 10:05 a.m.: 4 IR 2419; filed Dec 2, 1983, 2:43 p.m.: 7 IR 352; errata, 7 IR 1254; filed Dec 13, 1985, 9:13 a.m.: 9 IR 1036; filed Aug 18, 1986, 1:00 p.m.: 10 IR 24; filed May 15, 1998, 10:25 a.m.: 21 IR 3866; filed Jun 30, 2000, 4:18 p.m.: 23 IR 2719; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2506)

SECTION 2. 836 IAC 1-3-5 IS AMENDED TO READ AS FOLLOWS:

836 IAC 1-3-5 Emergency care equipment

Authority: IC 16-31-2-7
Affected: IC 16-31-3

Sec. 5. Each and every ambulance will have the following minimum emergency care equipment, and this equipment shall be assembled and readily accessible:

(1) Respiratory and resuscitation equipment as follows:

(A) Portable suction apparatus, capable of a minimum vacuum of three hundred (300) millimeters mercury, equipped with wide-bore tubing and both rigid and soft pharyngeal suction tips.

(B) On-board suction, capable of a minimum vacuum of three hundred (300) millimeters mercury, equipped with wide-bore tubing and both rigid and soft pharyngeal suction tips.

(C) Bag-mask ventilation units, hand operated, one (1) unit in each of the following sizes, each equipped with clear face masks and oxygen reservoirs with oxygen tubing:

(i) Adult.

(ii) Child.

(iii) Infant.

(iv) Neonatal (mask only).

(D) Oropharyngeal airways, two (2) each of adult, child, and infant.

(E) One (1) pocket mask with one-way valve.

(F) Portable oxygen equipment of at least three hundred (300) liters capacity (D size cylinder) with yoke, medical regulator, pressure gauge, and nondependent flowmeter.

(G) On-board oxygen equipment of at least three thousand (3,000) liters capacity (M size cylinder) with yoke, medical regulator, pressure gauge, and nondependent flowmeter.

(H) Oxygen delivery devices shall include the following:

(i) High concentration devices, two (2) each, adult, child, and infant.

(ii) Low concentration devices, two (2) each, adult.

(I) Nasopharyngeal airways, two (2) each of the following with water soluble lubricant:

(i) Small (20-24 french).

(ii) Medium (26-30 french).

(iii) Large (31 french or greater).

(J) Bulb syringe individually packaged in addition to obstetrics kit.

(K) Nonvisualized airway minimum of two (2) with water soluble lubricant.

(L) ~~Beginning January 1, 2000, every ambulance shall be required to have a~~ Semiautomatic or automated external defibrillator and a minimum of two (2) sets of pads.

(2) Wound care supplies as follows:

(A) Multiple trauma dressings, two (2) approximately ten (10) inches by thirty-six (36) inches.

(B) Fifty (50) sterile gauze pads, three (3) inches by three (3) inches or larger.

(C) Bandages, four (4) soft roller self-adhering type, two (2) inches by four (4) yards minimum.

(D) Airtight dressings, four (4), for open chest wounds.

(E) Adhesive tape, two (2) rolls.

(F) Burn sheets, two (2), sterile.

(G) Triangular bandages, four (4).

(H) Bandage shears, one (1) pair.

(3) Patient stabilization equipment as follows:
(A) Traction splint, lower extremity, limb-supports, padded ankle hitch, and traction strap, or equivalent, one (1) assembly in adult size.
(B) Upper and lower extremity splinting devices, two (2) each.
(C) One (1) splint device intended for the unit-immobilization of head-neck and torso. These items shall include the splint itself and all required accessories to provide secure immobilization.
(D) One (1) long back board with accessories to provide secure spinal immobilization.
(E) Rigid extrication collar, two (2) each capable of the following sizes:
(i) Pediatric.
(ii) Small.
(iii) Medium.
(iv) Large.
(F) One (1) ambulance litter with side rails, head-end elevating capacity, mattress pad, and a minimum of three (3) adjustable restraints to secure the chest, hip, and knee areas.
(4) Medications limited to, if approved by medical director, the following:
(A) Baby aspirin, eighty-one (81) milligrams each.
(B) Activated charcoal.
(C) Instant glucose.
(5) Personal protection/universal precautions equipment, minimum of two (2) each, including the following:
(A) Gowns.
(B) Face masks and shields.
(C) Gloves.
(D) Biohazard bags.
(E) Antimicrobial hand cleaner.
(6) Miscellaneous items as follows:
(A) Obstetrical kit, sterile, one (1).
(B) Clean linens consisting of the following:
(i) Pillow.
(ii) Pillow case.
(iii) Sheets and blankets.
(C) Blood pressure manometer, one (1) each in the following cuff sizes:
(i) Large adult.
(ii) Adult.
(iii) Pediatric.
(D) Stethoscopes, one (1) each in the following sizes:
(i) Adult.
(ii) Pediatric.
(E) Sharps collector, one (1) being a minimum of seven (7) inches in height.
(F) A current copy of the basic life support protocols.

(Indiana Emergency Medical Services Commission; Emergency Medical Services Rule II, E; filed Jun 5, 1975, 11:57 a.m.: Rules and Regs. 1976, p. 93; filed May 10, 1977, 10:52 a.m.: Rules and Regs. 1978, p. 219; filed Nov 3, 1980, 3:55 p.m.: 3 IR 2200; filed Dec 2, 1983, 2:43 p.m.: 7 IR 355; errata, 7 IR 1254; filed Dec 13, 1985, 9:13 a.m.: 9 IR 1045; filed Aug 18, 1986, 1:00 p.m.: 10 IR 31; filed May 15, 1998, 10:25 a.m.: 21 IR 3875; filed Jun 30, 2000, 4:18 p.m.: 23 IR 2727; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2507)

SECTION 3. 836 IAC 1-11-1 IS AMENDED TO READ AS FOLLOWS:

836 IAC 1-11-1 General certification provisions

Authority: IC 16-31-2-7
Affected: IC 4-21.5; IC 4-33; IC 5-2-5-1; IC 16-21; IC 16-31; IC 22-12-1-12

Sec. 1. (a) An organization eligible to be a certified emergency medical services nontransport provider shall be an established emergency services organization and shall be one (1) of the following:
(1) Fire department as defined in IC 22-12-1-12.
(2) Law enforcement agency as defined in IC 5-2-5-1.
(3) Hospital as licensed under IC 16-21.
(4) Any provider organization certified under IC 16-31.
(5) Indiana gaming organizations as defined in IC 4-33.
(6) Other organizations approved by the commission.

(b) Notwithstanding subsection (a), the commission, upon finding that the public health or safety is in imminent danger, may temporarily suspend a certificate without hearing for a period not to exceed ~~thirty (30)~~ **ninety (90)** days upon notice to the certificate holder.

(c) Upon suspension, revocation, or termination of a certificate, the provision of such service shall cease.

(d) After notice and hearing, the commission may, and is authorized to, suspend or revoke a certificate issued under IC 16-31 or impose a fine of up to five hundred dollars ($500) in accordance with section 5 of this rule, or both, for:
(1) fraud or misrepresentation in procuring certification; **or**
(2) failure to comply and maintain compliance with, or for violation of, any applicable provision, standard, or other requirement of IC 16-31 or this title.

The commission may initiate proceedings to suspend or revoke a certificate upon its own motion, or on the verified written complaint of any interested person, and all such proceedings shall be held and conducted in accordance with IC 4-21.5. *(Indiana Emergency Medical Services Commission; 836 IAC 1-11-1; filed May 15, 1998, 10:25 a.m.: 21 IR 3887; filed Jun 30, 2000, 4:18 p.m.: 23 IR 2728; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2508)*

SECTION 4. 836 IAC 1-11-2 IS AMENDED TO READ AS FOLLOWS:

836 IAC 1-11-2 Application for certification; renewal

Authority: IC 16-31-2-7
Affected: IC 16-31-3-2; IC 16-31-3-8

Sec. 2. (a) Application for emergency medical services nontransport provider certification shall be made on forms as prescribed by the commission, and the applicant shall comply with the following requirements:

(1) Applicants shall complete the required forms and submit the forms to the director not less than sixty (60) days prior to the requested effective date of the certificate.

(2) Each emergency medical services vehicle, with its equipment as required by this article, shall be made available for inspection by the director or the director's duly authorized representative.

(3) The premises on which emergency medical services vehicle supplies are stored shall be open during operating hours to the director or the director's duly authorized representative, for inspection.

(4) A complete listing of affiliated personnel to be utilized as emergency medical technicians, first responders, and emergency medical services vehicle drivers shall be submitted to the director. The director shall be notified in writing within thirty (30) days of any change in personnel.

(5) Each application shall include the following information:

(A) A description of the service area.

(B) Hours of operation.

(C) Number and location of emergency medical services vehicles.

(D) Organizational structure, including names, addresses, and telephone numbers of the owner, chief executive officer, chief operations officer, training officer, and medical director.

(E) Current Federal Communications Commission license or letter of authorization.

(F) Location of emergency medical services nontransport provider's records.

(G) Proof of insurance coverage in adequate amounts as specified in subsection (d) shall be submitted with the application and shall be renewed thirty (30) days prior to the expiration of the current insurance.

(H) Other information as required by the commission.

(b) Upon approval, a certificate shall be issued by the director. The certificate shall be valid for a period of ~~one (1) year~~ **two (2) years** unless earlier revoked or suspended by the commission and shall be prominently displayed at the place of business.

(c) Application for emergency medical services nontransport provider certification renewal shall be made not less than sixty (60) days prior to the expiration date of the current certificate to assure continuity of certification. Application for renewal shall be made on forms as prescribed by the commission and shall indicate compliance with the requirements set forth for original certification.

(d) Emergency medical services nontransport providers in states immediately adjacent to Indiana who will be providing emergency medical services vehicle service within Indiana under a contract with an Indiana local unit of government shall be certified by the Indiana emergency medical services commission in accordance with this article or apply for waiver of this article so long as the following requirements are met:

(1) The Indiana local unit of government shall meet the following requirements:

(A) Notify the Indiana emergency medical services commission of the intent to provide emergency medical services to residents of their area of responsibility when such services will be provided by an emergency medical services vehicle service in an adjacent state not certified by the Indiana emergency medical services commission and said emergency medical services vehicle service is unable to comply with this article for certification.

(B) Provide a copy of a legally binding contract for services that outlines the conditions under which emergency medical services will be provided.

(C) Show proof of the issuance of public notice that describes any and all differences between the state standards in existence for the contracted provider of emergency medical service and the standards adopted by the commission.

(D) The commission may issue certification under this provision for a period of ~~one (1) year.~~ **two (2) years.**

(2) The commission may revoke certification of the contracted emergency medical services nontransport provider immediately upon determining that the contracted emergency medical services nontransport provider is in violation of existing adjacent state rules and regulations regarding the provision of emergency medical services.

(3) Violations of Indiana patient care standards or standards existing under the contracted emergency medical services nontransport providers state rules and regulations are subject to the provision and levying of fines as described in 836 IAC 1-2-4 at the discretion of the director and shall be the responsibility of the Indiana local unit of government as the contractee.

(e) Emergency medical services nontransport providers shall submit a copy of an agreement between the nontransporting organization and an ambulance service provider certified pursuant to IC 16-31. The agreement shall ensure that the nontransporting organization can be assured that patients treated shall be transported in a timely and safe manner. The agreement shall not preclude another ambulance service provider, if available, from transporting the patients. *(Indiana Emergency Medical Services Commission; 836 IAC 1-11-2; filed May 15, 1998,*

10:25 a.m.: 21 IR 3887; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2509)

SECTION 5. 836 IAC 1-11-3 IS AMENDED TO READ AS FOLLOWS:

836 IAC 1-11-3 Emergency medical services nontransport provider operating procedures

Authority: IC 16-31-2-7
Affected: IC 16-18-2-7; IC 16-31-3-2; IC 34-6-2-49

Sec. 3. (a) The emergency medical services nontransport provider's premises shall be maintained, suitable to the conduct of the emergency medical services vehicle service, with provision for adequate storage and maintenance of equipment.

(b) Each emergency medical services nontransport provider shall provide for a periodic maintenance program to assure that all equipment is maintained in good working condition and that rigid sanitation procedures are in effect at all times.

(c) All emergency medical services nontransport provider premises, records, and equipment shall be made available for inspection by the commission, director, or a duly authorized representative at any time during operating hours.

(d) The insurance requirement of IC 16-31-3-2(a) is satisfied if the emergency medical services nontransport provider:

(1) has in force and effect public liability insurance in the sum of not less than three hundred thousand dollars ($300,000) combined single limit, issued by an insurance company licensed to do business in Indiana; or

(2) is a government entity within the meaning of IC 34-6-2-49.

Coverage shall be for each emergency medical services vehicle owned or operated by or for the emergency medical services nontransport provider.

(e) Each emergency medical services nontransport provider shall provide and maintain a communication system that meets or exceeds the requirements set forth in 836 IAC 1-4. The emergency medical services nontransporting vehicles are not required to be equipped with the Indiana hospital emergency radio network frequency (155.340 MHZ) as specified in 836 IAC 1-4-2(c)(2).

(f) Each emergency medical services nontransport provider shall designate one (1) person as the organization's training officer to assume responsibility for in-service training. This person shall be certified as a first responder, an emergency medical technician, an advanced emergency medical technician, a paramedic, a registered nurse, a certified physician assistant, or a licensed physician who is actively involved in the delivery of emergency medical services with that organization. The training officer shall be responsible for the following:

(1) Provide and maintain records of in-service training offered by the provider organization.

(2) Maintain the following in-service training session information:

(A) Summary of the program content.

(B) Names of instructors.

(C) Names of those attending.

(D) Date, time, and location of in-service training sessions.

(3) Sign individual emergency medical technician training records or reports to verify actual time in attendance at training sessions.

(g) An emergency medical services nontransport provider shall not act in a reckless or negligent manner so as to endanger the health or safety of emergency patients or members of the general public while in the course of business as an emergency medical services nontransport provider.

(h) Each emergency medical services nontransport provider shall notify the director within thirty (30) days of the present and past specific location of any emergency medical services vehicle if the location of the emergency medical services vehicle is changed from that specified in the provider's application for emergency medical services nontransport provider certification or certification renewal.

(i) Each emergency medical services nontransport provider shall ensure that rigid sanitation procedures are in effect at all times. The following sanitation standards apply to all emergency medical services vehicles:

(1) The equipment within the vehicle shall be clean and maintained in good working order at all times.

(2) Closed compartments shall be provided within the vehicle for medical supplies.

(3) Closed containers shall be provided for soiled supplies.

(4) Implements inserted into the patient's nose or mouth shall be single-service, wrapped, and properly stored and handled. Multi-use items are to be kept clean and sterile when indicated and properly stored.

(5) The equipment, utilized to treat a patient known to have a communicable disease or suffered exposure to hazardous material or biohazard material, shall be cleansed in accordance with current decontamination and disinfecting standards. All hazardous and biohazard materials shall be disposed of in accordance with current hazardous and biohazard disposition standards.

(j) An emergency medical services nontransport provider shall not engage in the provision of advanced life support as defined in IC 16-18-2-7.

(k) Each emergency medical services nontransport provider, under the responsibility of its chief executive officer and medical director, shall conduct quarterly audit and review to assess, monitor, and evaluate the quality of patient care as follows:

(1) The audit and review shall provide the following:

(A) An environment that encourages personnel to deliver care consistent with established standards of care.

(B) A systematic means of measuring and evaluating the quality of patient care.

(C) A tool to provide personnel with feedback and methods of action for improving practices and services.

(D) A method of identifying needs to staff development programs, basic training, in-service, and orientation.

(E) A method for describing patient care outcomes.

(2) The audit and review shall be conducted under the direction of one (1) of the following:

(A) The emergency medical services nontransport provider's medical director.

(B) An emergency room committee that is supervised by a medical director. Emergency medical services personnel shall serve as members on the committee.

(C) The emergency medical services nontransport provider that establishes a committee of individuals within the services.

(l) Each emergency medical services nontransport provider shall secure a medical director who shall be a physician with an unlimited license to practice medicine in Indiana. The duties and responsibilities of the medical director are as follows:

(1) Provide liaison between the local medical community and the emergency medical services provider.

(2) Assure compliance with defibrillation training standards and curriculum established by the commission.

(3) Monitor and evaluate the day-to-day medical operations of the emergency medical services organization.

(4) Assist in the continuing education programs of the emergency medical services organization.

(5) Provide technical assistance concerning the delivery of automated defibrillation and other medical issues.

(6) Provide individual consultation to the emergency medical personnel affiliated with the emergency medical services organization.

(7) Participate in the audit and review of cases treated by the emergency medical defibrillation personnel of the emergency medical services organization.

(8) Assure compliance with approved medical standards established by the commission performed by the organization.

(9) Establish protocols for automatic defibrillation, airway management, ~~wound care,~~ ~~patient stabilization,~~ and medication administration as approved by the commission.

(m) All records shall be retained for a minimum of three (3) years, except for the following records which shall be retained for a minimum of seven (7) years:

(1) Audit and review records.

(2) Run reports.

(3) Training records.

(n) Each emergency medical services nontransport provider shall employ at least one (1) certified person trained in the use of the automated defibrillator. Only trained, certified emergency medical services personnel shall use an automated defibrillator.

(o) Each emergency medical services nontransport provider shall maintain, in a manner prescribed by the commission, accurate records, including a run report form, concerning the assessment and treatment of each emergency patient treated. The run report form shall include the following information about the patient:

(1) Name.

(2) Identification number.

(3) Age.

(4) Sex.

(5) Race.

(6) Physician of the patient.

(7) Date of birth.

(8) Address, including zip code.

(9) Location of incident.

(10) Chief complaint.

(11) History, including the following:

(A) Current medical condition and medications.

(B) Past pertinent medical conditions and allergies.

(12) Physical examination section.

(13) Treatment given section.

(14) Vital signs, including the following:

(A) Pulse.

(B) Respirations.

(C) Level of consciousness.

(D) Skin temperature and color.

(E) Pupillary reactions.

(F) Ability to move.

(G) Presence or absence of breath sounds.

(H) The time of observation and a notation of the quality for each vital sign should also be included.

(15) Responsible guardian.

(16) Name of patient attendants, including emergency medical services certification numbers.

(17) Vehicle emergency medical services certification number.

(18) Responding service delivery times, including the following:

(A) Time of receipt of call.

(B) Time dispatched.

(C) Time arrived scene.

(D) Time of patient released to transporting emergency medical services.

(E) Time vehicle available for next response.

(19) Date of service.

(20) The report form shall provide space for narrative description of the situation and the care rendered by the nontransport unit.

(p) A signed statement for refusal of treatment or transporta-

tion services, or both, shall be maintained as part of the run documentation.

(q) All emergency medical services nontransport providers shall participate in the emergency medical services system review by:

(1) collecting all data elements prescribed by the commission; and

(2) reporting that information according to procedures and schedules prescribed by the commission.

(r) Each emergency medical services nontransport provider shall comply with the general certification provision of this article. *(Indiana Emergency Medical Services Commission; 836 IAC 1-11-3; filed May 15, 1998, 10:25 a.m.: 21 IR 3888; filed Jun 30, 2000, 4:18 p.m.: 23 IR 2729; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2510)*

SECTION 6. 836 IAC 2-2-1 IS AMENDED TO READ AS FOLLOWS:

836 IAC 2-2-1 General requirements for paramedic organizations

Authority: IC 16-31-2-7
Affected: IC 4-21.5; IC 16-31-3

Sec. 1. (a) Certification by the commission is required for any ambulance service provider who seeks to provide advanced life support services as a paramedic organization unless provisional certification is issued pursuant to subsection (p).

(b) If the paramedic organization also provides transportation of emergency patients, the paramedic organization shall be certified as an ambulance service provider in accordance with the requirements specified in 836 IAC 1 pursuant to IC 16-31. The paramedic nontransport organizations shall meet the requirements specified in 836 IAC 1-2-2(a) and 836 IAC 1-11-3(o) through 836 IAC 1-11-3(q).

(c) The paramedic organization shall ensure that:

(1) ambulances used are certified and meet the requirements specified in 836 IAC 1-3; and

(2) all nontransport emergency medical services vehicles used for the provision of advanced life support meet all of the requirements in 836 IAC 2-14.

(d) Paramedic organizations shall have a contract, or interdepartmental memo if hospital based, with one (1) or more supervising hospitals for the following services:

(1) Continuing education.

(2) Audit and review.

(3) Medical control and direction.

(4) Provision of arrangements and the supervision of arrangements for the supply of medications and other items utilized by emergency medical service clinical personnel in the provision of advanced life support service.

(5) Provision to allow the paramedics affiliated with the supervised paramedic organization to function within the appropriate hospital department in order to obtain continuing practice in their clinical skills.

The contract or interdepartmental memo shall include a detailed description of how such services shall be provided to the paramedic organization. In those cases where more than one (1) hospital contracts, or seeks to contract, with a paramedic provider organization as a supervising hospital, an interhospital agreement shall be provided to the commission that shall clearly define the specific duties and responsibilities of each hospital to ensure medical and administrative accountability of system operation.

(e) The paramedic organization shall have a medical director provided by the paramedic organization, or jointly with the supervising hospital, who shall be a physician who holds a currently valid unlimited license to practice medicine in Indiana and has an active role in the delivery of emergency care. The medical director is responsible for providing competent medical direction as established by the medical control committee. Upon establishment of a medical control policy, the paramedic organization medical director and the chief executive officer have the duty to enact the policy within the paramedic organization and accordingly enforce the policy. The duties and responsibilities of the medical director include, but are not limited to, the following:

(1) Provide liaison with physicians and the medical community.

(2) Assure that the drugs, medications, supplies, and equipment are available to the paramedic organization.

(3) Monitor and evaluate day-to-day medical operations of paramedic organizations.

(4) Assist in the provision and coordination of continuing education.

(5) Provide information concerning the operation of the paramedic organization.

(6) Provide individual consultation to paramedics.

(7) Participate in at least quarterly audit and review of cases treated by paramedics of the ~~supervising hospital.~~ **provider organization.**

(8) Attest to the competency of paramedics affiliated with the paramedic organization to perform skills required of a paramedic under ~~836 IAC 2-6.~~ **836 IAC 4-9-5.**

(9) Establish protocols for advanced life support.

(10) Establish and publish a list of medications, including minimum quantities and dosages to be carried on vehicle.

(f) The paramedic organization shall maintain a communications system that shall be available twenty-four (24) hours a day between the paramedic organization and the emergency department, or equivalent, of the supervising hospital using UHF (ultra high frequency) voice communications. The communications system shall be licensed by the Federal Communications Commission.

(g) Each paramedic organization shall do the following:
(1) Maintain an adequate number of trained personnel and emergency response vehicles to provide continuous, twenty-four (24) hour advanced life support services.
(2) Notify the commission in writing within thirty (30) days of assigning any individual to perform the duties and responsibilities required of a paramedic. This notification shall be signed by the provider organization and medical director of the provider organization.
(3) Notify the commission in writing within thirty (30) days of a paramedic's termination of employment or for any reason which prohibits a certified individual from performing the procedures required of a paramedic.

(h) Each ambulance used for the purpose of providing advanced life support services, when dispatched on an emergency run, shall be staffed by not less than two (2) persons, one (1) of whom is certified as a paramedic and the other certified as an emergency medical technician pursuant to IC 16-31, except, if the ambulance is used in conjunction with a nonambulance vehicle certified by the commission for the provision of advanced life support, it shall be staffed by at least one (1) emergency medical technician certified pursuant to IC 16-31. However, each nontransport vehicle used for the purpose of providing advanced life support services when dispatched on an emergency run need only to be staffed, as a minimum, by a certified paramedic.

(i) When advanced life support services administered by paramedics at the scene of an accident or illness are continued en route to an emergency facility, as a minimum, the patient compartment of the ambulance shall be staffed by not less than one (1) person who is certified as a paramedic.

(j) The paramedic organization shall notify the commission in writing within thirty (30) days of any change in the services provided.

(k) No certification is required for the following:
(1) A person who provides advanced life support while assisting in the case of a major catastrophe or disaster, whereby persons who are certified to provide emergency medical services or advanced life support are insufficient or are unable to cope with the situation.
(2) An agency or instrumentality of the United States and any paramedics of such agency or instrumentality is not required to be certified nor to conform to the standards prescribed in this article.

(l) After proper notice and hearing, the commission may:
(1) levy penalties up to five hundred dollars ($500) in accordance with 836 IAC 1-2-4 and 836 IAC 2-13-1; or
(2) suspend or revoke a certificate issued under this article for:
(A) fraud or misrepresentation in procuring certification;
(B) failure to comply and maintain compliance; or
(C) violation of any applicable provisions, standards, or other requirements of this article.

(m) The commission may initiate proceedings to levy fines up to five hundred dollars ($500) in accordance with 836 IAC 1-2-4 and 836 IAC 2-13-1 or suspend or revoke a certificate upon its own motion or on the verified written complaint of any interested person, and all such proceedings shall be held and conducted in accordance with the provisions of IC 4-21.5.

(n) Notwithstanding the provisions of this article, the commission, upon finding that the public health or safety is in imminent danger, may temporarily suspend a certificate without hearing for a period not to exceed ~~thirty (30)~~ **ninety (90)** days upon notice to the certificate holder.

(o) Upon suspension, revocation, or termination of a certificate, the provision of advanced life support services shall cease.

(p) The director may issue a provisional certification for the provision of advanced life support as a paramedic organization to an ambulance service provider certified pursuant to IC 16-31 only, or to an advanced emergency medical technician organization certified pursuant to IC 16-31, for the purpose of prehospital training of paramedic students when in the presence of a preceptor or preceptors approved by the commission, upon demonstration by the applicant to the satisfaction of the director that the ambulance to be used for such training is certified pursuant to IC 16-31 and meets the requirements of subsection (f) and section 3 of this rule, and that the ambulance service provider or advanced emergency medical technician organization has and shall maintain an adequate number of paramedic students, preceptors, and ambulances to provide continuous twenty-four (24) hour advanced life support service. Application for provisional certification shall be made on such forms as prescribed by the commission, which shall be fully completed. The director may issue a provisional certificate for a period not to exceed sixty (60) days beyond the date of the paramedic course completion as identified on the approved course application. However, the director shall not issue a provisional certificate for a period exceeding twenty-four (24) consecutive months from the starting date of the course as identified on the approved course application. The issuance of a temporary or full certification invalidates any provisional certification.

(q) The paramedic organization shall, with medical director and chief executive officer approval, allow a graduate of an Indiana approved paramedic course to perform advanced life support under the direction of a preceptor. This person shall be actively pursuing certification as an Indiana certified paramedic. This provision shall be limited from one (1) year from date of course completion as indicated on course report.

(r) Provide for a periodic maintenance program to assure that emergency response vehicles, including equipment, are main-

tained in good working condition and that strict sanitation procedures are in effect at all times.

(s) Paramedic organization premises, records, parking, or garaging facilities and response vehicles shall be available for inspection by the director, or the director's duly authorized representative, at any time during operating hours.

(t) Each paramedic organization shall have in force and effect public liability insurance in the sum as described in 836 IAC 1-2-3(g) pursuant to IC 16-31. Such proof of insurance shall be made on a form prescribed by the commission.

(u) Each nontransport vehicle used for the purpose of providing advanced life support services when dispatched on an emergency run need only to be staffed, as a minimum, by a certified paramedic. *(Indiana Emergency Medical Services Commission; Advanced Life Support Rule I, A; filed Jan 21, 1977, 11:30 a.m.: Rules and Regs. 1978, p. 200; filed Dec 15, 1977: Rules and Regs. 1978, p. 250; filed Nov 3, 1980, 3:55 p.m.: 3 IR 2216; filed Oct 13, 1981, 10:05 a.m.: 4 IR 2434; errata, 5 IR 400; filed Dec 2, 1983, 2:43 p.m.: 7 IR 364; errata, 7 IR 1254; filed Dec 13, 1985, 9:13 a.m.: 9 IR 1062; filed Aug 18, 1986, 1:00 p.m.: 10 IR 41; filed Oct 11, 1988, 11:05 a.m.: 12 IR 358; filed May 15, 1998, 10:25 a.m.: 21 IR 3892; filed Jun 30, 2000, 4:18 p.m.: 23 IR 2733; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2512)*

SECTION 7. 836 IAC 2-4.1-2 IS AMENDED TO READ AS FOLLOWS:

836 IAC 2-4.1-2 Certification as a supervising hospital; renewal

Authority: IC 16-31-2-7
Affected: IC 16-31-3

Sec. 2. Hospitals seeking commission certification shall meet the following minimum requirements:

(1) Have an emergency department open and staffed by a physician twenty-four (24) hours a day.

(2) The hospital's administration shall have approved a written contractual agreement, **or interdepartmental memo if hospital based,** with one (1) or more emergency medical services provider organizations that furnish advanced life support service. The contract shall include a detailed description of the following services to be provided by the hospital to the certified emergency medical service provider organization:

(A) Continuing education.

(B) Audit and review.

(C) Medical control and direction.

(D) Provision of arrangements and the supervision of arrangements for the supply of medications and other items utilized by emergency medical service clinical personnel in the provision of advanced life support service.

(E) Provision and supervision of arrangements that allow the emergency medical services clinical personnel affiliated with the supervised emergency medical service provider to function within appropriate hospital departments in order to obtain continuing practice in their clinical skills.

(3) Provide and maintain a voice communication system between the emergency medical service provider organization response personnel and the hospital's emergency department. The communications system shall be licensed by the Federal Communications Commission.

(4) The hospital shall provide a physician or physician designate, authorized in writing by the hospital's medical staff, who is at all times immediately available to supervise the medical procedures performed by the emergency medical service provider organization's clinical personnel via the voice communication system.

(5) The hospital shall establish a process for the audit and review of medical procedure performed by the clinical personnel of the emergency medical service provider organization. ~~in order to~~ **Requirements for audit and review are as follows:**

(A) The audit shall ensure an appropriate level of compliance with medical protocols and appropriate level of skill in the performance of medical techniques by those personnel.

(B) The results of the audit shall be reviewed with the emergency medical service personnel.

(C) Documentation for the audit shall include the following:

(i) The criteria used to select audited runs.

(ii) Problem identification and resolution.

(iii) Date of review.

(iv) Attendance at the review.

(v) A summary of the discussion at the review.

(D) The audit and review shall be conducted by the medical control committee as defined in subdivision (9).

(6) The supervising hospital shall ~~do the following annually:~~

~~(A)~~ review **and approve the in-service of the certified paramedics affiliated with** the ~~competency of the clinical personnel of the~~ emergency medical services provider organization.

~~(B)~~ **(7)** Send a roster of clinical personnel ~~affiliated~~ **whose sole advanced life support affiliation is** with the supervising hospital. ~~and emergency medical services provider organizations to the commission.~~

~~(7)~~ **(8)** The supervising hospital shall report in writing any changes, including affiliated clinical personnel, within thirty (30) days.

~~(8)~~ **(9)** The supervising hospital shall establish a medical control committee for audit and review of medical procedures perform by the advanced life support personnel and establish policies for medical direction and control. The membership of the medical control committee shall be as follows:

(A) Medical director of provider organization.

(B) Emergency department supervisory personnel.

(C) Provider organization supervisory personnel.

(D) EMS educator.

(E) Advanced life support personnel of appropriate level from provider organization.

(Indiana Emergency Medical Services Commission; 836 IAC 2-4.1-2; filed May 15, 1998, 10:25 a.m.: 21 IR 3899; filed Jun 30, 2000, 4:18 p.m.: 23 IR 2737; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2514)

SECTION 8. 836 IAC 2-7.1-1 IS AMENDED TO READ AS FOLLOWS:

Rule 7.1. Advanced EMT Provider Organizations; Requirements; Standards

836 IAC 2-7.1-1 Advanced emergency medical technician organizations; general requirements

Authority: IC 16-31-2-7
Affected: IC 4-21.5; IC 16-31-3

Sec. 1. (a) The advanced emergency medical technician provider organization certification provides authority to perform skills set forth and approved by the commission for which certification is granted. The medical director may limit the skills according to local protocols.

(b) Certification by the commission is required for any ambulance service provider who seeks to provide advanced life support services as an advanced emergency medical technician organization unless provisional certification is issued pursuant to subsection (o).

(c) If the advanced emergency medical technician organization also provides transportation of emergency patients, the advanced emergency medical technician organization shall be certified as an ambulance service provider in accordance with the requirements specified in 836 IAC 1. The advanced emergency medical technician nontransport organization shall meet the requirements specified in 836 IAC 1-2-2(a), and 836 IAC 1-11-3(o) through 836 IAC 1-11-3(q).

(d) The advanced emergency medical technician organization shall ensure that:

(1) the ambulances used are certified and meet the requirements specified in 836 IAC 1-3; and

(2) all nontransport emergency medical services vehicles used for the provision of advanced life support meet all of the requirements required in 836 IAC 2-14.

(e) The advanced emergency medical technician organization shall have agreed by contract or interdepartmental memo if it is a hospital based organization with one (1) or more supervising hospitals for the following services:

(1) Continuing education.

(2) Audit and review.

(3) Medical control and direction.

(4) Liaison and direction for supply of intravenous fluids and other items utilized by advanced emergency medical technicians.

(5) Provision to allow the advanced emergency medical technicians affiliated with the supervised advanced emergency medical technician organization to function within appropriate hospital departments in order to obtain continuing practice in their clinical skills.

The contract shall include a detailed description of how such services shall be provided to the advanced emergency technician organization. In those cases where more than one (1) hospital contracts, or seeks to contract with, an advanced emergency medical technician organization as a supervising hospital, an interhospital agreement shall be provided to the commission that shall clearly define the specific duties and responsibilities of each hospital to ensure medical and administrative accountability of system operation.

(f) The advanced emergency medical technician organization shall have a medical director provided by the advanced emergency medical technician organization, or jointly with the supervising hospital, who is a physician who

~~(1)~~ holds a currently valid unlimited license to practice medicine in Indiana and

~~(2)~~ has an active role in the delivery of emergency care.

The medical director is responsible for providing competent medical direction as established by the medical control committee and overall supervision of the medical aspect of the advanced emergency medical technician organization. Upon establishment of a medical control policy, the advanced emergency medical technician organization medical director and the chief executive officer have the duty to enact the policy within the advanced emergency medical technician organization and accordingly enforce the policy. The duties and responsibilities of the medical director include, but are not limited to, the following:

~~(A)~~ **(1)** Providing liaison with physicians.

~~(B)~~ **(2)** Assuring that appropriate intravenous solutions, supplies, and equipment are available to the advanced emergency medical technician organization.

~~(C)~~ **(3)** Monitor and evaluate day-to-day medical operation.

~~(D)~~ **(4)** Assist the supervising hospital in the coordination of in-service training programs.

~~(E)~~ **(5)** Provide information concerning the operation of the advanced emergency medical technician organization.

~~(F)~~ **(6)** Provide individual consultation to advanced emergency medical technicians.

~~(G)~~ **(7)** Assure continued competence of advanced emergency medical technicians affiliated with, or employed by, the advanced emergency medical technician organization.

~~(H)~~ **(8)** Participate in the quarterly audit and review of cases treated by advanced emergency medical technicians **of the provider organization.**

~~(I)~~ **(9)** Establish protocols for advanced life support.

~~(J)~~ **(10)** Establish and publish a list of intravenous fluids and

administration supplies, including minimum quantities to be carried on the vehicle.

(g) Each advanced emergency medical technician organization shall:

(1) maintain an adequate number of trained personnel and emergency response vehicles to provide continuous twenty-four (24) hour advanced life support services;

(2) notify the commission in writing within thirty (30) days of assigning any individual to perform the duties and responsibilities required of an advanced emergency medical technician, and this notification shall be signed by the provider organization and medical director of the provider organization; and

(3) notify the commission in writing within thirty (30) days if an advanced emergency medical technician:

(A) terminates employment; ~~or~~

(B) **terminates** affiliation; or

(C) for any reason is prohibited from performing the procedures for which certification was granted.

(h) When advanced life support services administered by advanced emergency medical technicians at the scene of an accident or illness are continued en route to an emergency facility, as a minimum, the patient compartment of the ambulance shall be staffed by not less than one (1) person certified as an advanced emergency medical technician.

(i) The advanced emergency medical technician organization shall notify the commission in writing within thirty (30) days of any change in the advanced life support services provided for which certification was granted.

(j) No certification is required for the following:

(1) ~~For~~ A person who provides advanced life support while assisting in the case of a major catastrophe disaster whereby persons who are certified to provide emergency medical services or advanced life support are insufficient or are unable to cope with the situation.

(2) ~~For~~ An agency or instrumentality of the United States and any advanced emergency medical technicians of such agency or instrumentality ~~is~~ **are** not required to be certified nor to conform to the standards prescribed in this article unless the agency or instrumentality seeks to provide service to citizens of Indiana off of the federal area.

(k) After proper notice and hearing, the commission may:

(1) levy penalties up to five hundred dollars ($500) in accordance with 836 IAC 1-2-4 and 836 IAC 2-13-1; or

(2) suspend or revoke a certificate issued under this article for:

(A) fraud or misrepresentation in procuring certification;

(B) failure to comply and maintain compliance with; or

(C) violation of any applicable provisions, standards, or other requirements of this article.

(l) The commission may initiate proceedings to suspend or revoke a certificate upon its own motion or on the verified written complaint of any interested person, and all such proceedings shall be held and conducted in accordance with IC 4-21.5.

(m) Notwithstanding the provisions of this article, the commission, upon finding that the public health or safety is in imminent danger, may temporarily suspend a certificate without hearing for a period not to exceed ~~thirty (30)~~ **ninety (90)** days upon notice to the certificate holder.

(n) Upon suspension, revocation, or termination of a certificate, the provision of advanced life support services shall cease.

(o) The director may issue a provisional certification for the provision of advanced life support as an advanced emergency medical technician organization to an ambulance service provider certified pursuant to IC 16-31 for the purpose of prehospital training of advanced emergency medical technician students when in the presence of a preceptor approved by the commission upon demonstration by the applicant to the satisfaction of the director that:

(1) the ambulance to be used for such training is certified pursuant to IC 16-31 and meets the requirements of this article; and

(2) the ambulance service provider has and will maintain an adequate number of advanced emergency medical technician students, preceptors, and ambulances to provide continuous twenty-four (24) hour advanced life support service.

Application for provisional certification shall be made on forms as prescribed by the commission, which shall be fully completed. The director may issue a provisional certificate for a period not to exceed sixty (60) days beyond the date the advanced emergency medical technician course completion as identified on the approved course application. However, the director shall not issue a provisional certificate for a period exceeding six (6) consecutive months from the starting date of the course as identified on the approved course application. The issuance of certification invalidates any provisional certification.

(p) Provide for a periodic maintenance program to assure that:

(1) emergency response vehicles, including equipment, are maintained in good working condition; and

(2) applicable sanitation procedures are in effect at all times.

(q) Advanced emergency medical technician organization premises, records, parking, or garaging facilities and response vehicles shall be available for inspection by the director, or the director's duly authorized representative, at any time during operating hours.

(r) Each advanced emergency medical technician organization shall have in force and effect public liability insurance in the

sum as described in 836 IAC 1-2-3(g) pursuant to IC 16-31. Such proof of insurance shall be made on a form prescribed by the commission.

(s) The advanced emergency medical technician organization shall maintain a communications system that shall be available twenty-four (24) hours a day between the advanced emergency medical technician organization and the emergency department, or equivalent, of the supervising hospital using voice communications. The communications system shall be licensed by the Federal Communications Commission.

(t) Each nontransport vehicle used for the purpose of providing advanced life support services when dispatched on an emergency run need only to be staffed, as a minimum, by a certified advanced emergency medical technician. *(Indiana Emergency Medical Services Commission; 836 IAC 2-7.1-1; filed Apr 6, 1988, 9:55 a.m.: 11 IR 2875; filed May 15, 1998, 10:25 a.m.: 21 IR 3904; filed Jun 30, 2000, 4:18 p.m.: 23 IR 2738; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2515)*

SECTION 9. 836 IAC 4-7-3.5 IS ADDED TO READ AS FOLLOWS:

836 IAC 4-7-3.5 Continuing education requirements

Authority: IC 16-31-2-7
Affected: IC 16-31-3

Sec. 3.5. Advanced emergency medical technicians seeking certification renewal shall meet or exceed the minimum requirements in this section to maintain their certification. Concurrent emergency medical technician certification shall be maintained if the individual completes and reports to the commission fifty-six (56) hours of continuing education according to the following:

(1) Participate in a minimum of thirty-four (34) hours of any combination of lecture, critiques, skills proficiency examination, continuing education course, or teach *[sic., teaching]* **sessions that review subject matter presented in the Indiana basic emergency medical technician curriculum.**

(2) Participate in a minimum of ten (10) hours of any combination of lecture, critiques, skills proficiency examination, or teaching sessions that review subject matter presented in the Indiana advanced emergency medical technician curriculum.

(3) Participate in a minimum of twelve (12) hours of audit and review.

(4) Participate in any update course as prescribed by the commission.

(5) Successfully complete a proficiency evaluation that tests the skills presented in the Indiana basic emergency medical technician curriculum and the Indiana advanced emergency medical technician curriculum.

(Indiana Emergency Medical Services Commission; 836 IAC 4-7-3.5; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2517)

SECTION 10. 836 IAC 4-9-2.5 IS ADDED TO READ AS FOLLOWS:

836 IAC 4-9-2.5 Inactive status for an Indiana certified paramedic

Authority: IC 16-31-2-7
Affected: IC 16-31-3

Sec. 2.5. (a) A paramedic requesting inactive paramedic status shall be currently certified in Indiana as a paramedic and be an individual who has previously recertified as a paramedic in Indiana at least one (1) time. The individual's certification must be in good standing with the commission at the time inactive status is granted. Applicants for inactive status do not have to be affiliated with a paramedic provider organization. Applicants wanting inactive status shall submit a request in writing to the commission.

(b) If a paramedic wants to keep an active emergency medical technician certification, the paramedic shall meet the requirements set forth in 836 IAC 4.4 *[sic., 836 IAC 4-4]***.**

(c) Paramedics on inactive status must collect the following continuing education hours during the inactive period, and the continuing education hours must be reported to the commission prior to the expiration date of the certificate:

(1) Collect and report continuing education requirements listed in section 5(b)(1) through (5)(b)(3) of this rule.

(2) Collect and report twelve (12) additional continuing education hours.

(d) Paramedics with an inactive status wishing to return to active status must meet the following requirements:

(1) Comply with subsection (b) during inactive status.

(2) Be affiliated with an Indiana certified paramedic provider organization or an Indiana certified paramedic supervising hospital by submitting a signed application for advanced life support.

(3) Submit in writing a verified statement attesting to the applicant's competency in skills listed in section 5(b)(5) of this rule signed by the paramedic provider medical director.

Upon completion of these requirements, the emergency medical technician certification will become active. *(Indiana Emergency Medical Services Commission; 836 IAC 4-9-2.5; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2517)*

SECTION 11. 836 IAC 4-10 IS ADDED TO READ AS FOLLOWS:

Rule 10. Penalties

836 IAC 4-10-1 Penalties

Authority: IC 16-31-3-14
Affected: IC 4-21.5-3; IC 16-31-2-7; IC 16-31-2-9; IC 16-31-3-17; IC 16-31-10-1

Sec. 1. (a) The commission or director may penalize a person certified under this article up to five hundred dollars ($500) per occurrence for a violation of patient care standards, protocols, or rules established by the commission.

(b) A penalty may be imposed only after a hearing or the imposition of a penalty resulting from a hearing has been held by the commission, director, or the director's designee pursuant to IC 4-21.5-3.

(c) As used in this section, "per occurrence" means a violation of patient care standards, protocols, or rules established by the commission that remains uncorrected for each twenty-four (24) hour period after identification by the director or the director's designee.

(d) The director or commission may assess penalties up to five hundred dollars ($500) per occurrence for the following violations:

(1) Patient care standards or protocols.

(2) Training requirements.

(3) Individual certification requirements.

(4) Failure to comply with this title.

(Indiana Emergency Medical Services Commission; 836 IAC 4-10-1; filed Apr 4, 2002, 9:15 a.m.: 25 IR 2517)

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TITLE 872 INDIANA BOARD OF ACCOUNTANCY

LSA Document #01-310(F)

DIGEST

Amends 872 IAC 1-1-8 to change the experience requirements for certified public accountants to bring the requirements into conformity with statutory changes by changing the types of experience required before a certificate or license may be issued. Amends 872 IAC 1-1-8.3 to require a licensee to verify an applicant's experience to meet the requirements of IC 25-2.1-3-10. Amends 872 IAC 1-1-8.4 to revise the use of an advanced degree as experience. Amends 872 IAC 1-1-10 to revise the fee schedule for certificate of registration for CPAs, PAs, and APs and for firm permits. Repeals 872 IAC 1-1-8.1. Effective 30 days after filing with the secretary of state.

872 IAC 1-1-8 **872 IAC 1-1-8.4**
872 IAC 1-1-8.1 **872 IAC 1-1-10**
872 IAC 1-1-8.3

SECTION 1. 872 IAC 1-1-8 IS AMENDED TO READ AS FOLLOWS:

872 IAC 1-1-8 Experience requirements; credit for types of experience

Authority: IC 25-2.1-2-15
Affected: IC 20-12-61; IC 20-12-62; IC 25-2.1-3-10

Sec. 8. (a) This section and sections ~~8.1~~ **8.2** through 8.5 of this rule implement the requirements in IC 25-2.1-3-10 for experience to be obtained by applicants for certified public accountant certificates before the certificate or license may be issued by the board. The experience requirements are **twenty-four (24) months of** full-time employment in the following positions:

~~(1) Thirty-six (36) months of practice in another state as a certified public accountant or as a public accountant.~~

~~(2) Thirty-six (36) months~~ **(1)** As an employee **or an accounting intern** engaged ~~as an accountant~~ **in an accounting position** in a firm (as that term is defined in 872 IAC 1-0.5-1(11)).

~~(3) Thirty-six (36) months in an accounting internship with a firm.~~

~~(4) Forty-three (43) months as a field examiner for the state board of accounts, department of insurance, or department of financial institutions.~~

~~(5) Forty-three (43) months in an accounting internship with the state board of accounts.~~

~~(6) Fifty-four (54) months in a corporate internal audit position.~~

~~(7) Sixty (60) months supervising the accounting and reporting function for a business or corporation in the position of chief financial officer, chief accounting officer, controller, or other similar position.~~

~~(8) Sixty (60) months as a field auditor for the department of state revenue.~~

~~(9) Sixty (60) months as an Internal Revenue Service examiner.~~

(2) As an employee in a financial or accounting position in industry, government, or a nonprofit organization.

(3) As an employee in an advisory and/or consulting services position related to one (1) or more of the following activities:

(A) Financial.

(B) Accounting.

(C) Operational.

~~(10) Sixty (60) months~~ **(4) As an instructor** teaching accounting in a college or university (four (4) year institutions or junior colleges).

~~(11) Seventy-two (72) months in an accounting internship~~

~~with a business or corporation or with a governmental agency, except the state board of accounts.~~

~~(12)~~ ~~Seventy-two (72) months~~ **(5) As an instructor** teaching accounting in an institution created under ~~IC 20-12-61~~ **IC 25-12-61** *[sic., IC 20-12-61]* or private school registered under IC 20-12-62.

~~(13) Governmental or industrial accounting positions not described elsewhere in this subsection shall require no less than seventy-two (72) months. The time required shall depend upon the following:~~

~~(A) The amount and variety of the accounting, financial reporting, tax planning, and statutory compliance (such as Securities and Exchange Commission reports and income tax returns).~~

~~(B) Composition of the position.~~

~~(C) The accounting qualifications and experience of the immediate superior.~~

(b) Clerical functions shall not count under this ~~subdivision~~ **section** toward meeting the experience requirements. Clerical functions are positions that do not have accounting significance, including doing merely mathematical calculations, account analysis (looking into accounting books for specific information already recorded), and merely recording information in the general ledger (as opposed to compiling the information). Positions that partly qualify under this ~~subdivision~~ **section** and partly do not qualify shall be treated under ~~the~~ **this** method provided for in section 8.2 of this rule with the part of the position that does **not** qualify under this ~~subdivision~~ **section** being treated as if it were part-time employment.

~~(b)~~ **(c)** Experience in fractions of months will be counted.

(d) An applicant may combine the types of experience described in subsection (a) of this rule. To do so, the applicant must obtain a total of twenty-four (24) months of experience. *(Indiana Board of Accountancy; Rule 69-1,8; filed Jun 30, 1978, 9:54 a.m.: 1 IR 396; filed Aug 18, 1983, 3:20 p.m.: 6 IR 1928; filed Mar 20, 1985, 3:25 p.m.: 8 IR 1033; filed Aug 28, 1986, 3:20 p.m.: 10 IR 65; filed Nov 28, 1988, 5:32 p.m.: 12 IR 922; filed Jun 1, 1994, 5:00 p.m.: 17 IR 2343; errata filed Sep 14, 1994, 2:50 p.m.: 18 IR 269; filed Feb 21, 2000, 7:06 a.m.: 23 IR 1651; readopted filed Jun 22, 2001, 8:57 a.m.: 24 IR 3824; filed Apr 4, 2002, 9:28 a.m.: 25 IR 2518)*

SECTION 2. 872 IAC 1-1-8.3 IS AMENDED TO READ AS FOLLOWS:

872 IAC 1-1-8.3 Experience verification
Authority: IC 25-2.1-2-15
Affected: IC 20-12-61; IC 20-12-62; IC 25-2.1-3-10

Sec. 8.3. **(a)** An applicant's experience in a particular position meets the ~~supervision or direction~~ **requirements** in IC 25-2.1-3-10 if the work ~~was under the supervision or direction requirement of an individual with an active license and that individual:~~ **is verified by a licensee who:**

(1) employed the applicant or a legal entity controlled by that individual employed the applicant;

(2) worked for the same employer as the ~~applicant; or~~ **applicants;**

(3) reviewed the accounting work of the applicant on a periodic basis in the capacity of an outside accounting firm, a government agency, or some similar capacity; **or**

(4) otherwise has direct knowledge of the work performed by the applicant.

(b) Any licensee who has been requested by an applicant to submit to the board verification of the applicant's experience and has refused to do so shall, upon request by the board, explain in writing or in person the basis for such refusal. *(Indiana Board of Accountancy; 872 IAC 1-1-8.3; filed Feb 21, 2000, 7:06 a.m.: 23 IR 1653; readopted filed Jun 22, 2001, 8:57 a.m.: 24 IR 3824; filed Apr 4, 2002, 9:28 a.m.: 25 IR 2519)*

SECTION 3. 872 IAC 1-1-8.4 IS AMENDED TO READ AS FOLLOWS:

872 IAC 1-1-8.4 Advanced degree as experience
Authority: IC 25-2.1-2-15
Affected: IC 20-12-61; IC 20-12-62; IC 25-2.1-3-10

Sec. 8.4. (a) A master's degree in accounting or business administration from a college or university recognized by the board may be substituted for ~~one (1) year~~ **twelve (12) months** of ~~public~~ accounting experience for any person who ~~has met the education requirement outlined in section 6 of this rule and~~ was a first time examination candidate prior to January 1, 2000.

(b) A doctorate degree in accounting or business administration from a college or university recognized by the board may be substituted for ~~one (1) year~~ **twelve (12) months** of ~~public~~ accounting experience. ~~for any person who has met the education requirement outlined in section 6 or section 6.1 of this rule.~~

(c) For ~~the~~ purposes of this section, an advanced degree shall be calculated ~~in the same manner~~ as twelve (12) months of ~~employment in a firm~~ **experience** under section ~~8(a)(2)~~ **8** of this rule.

(d) An applicant may not receive experience credit from more than one (1) advanced degree. *(Indiana Board of Accountancy; 872 IAC 1-1-8.4; filed Feb 21, 2000, 7:06 a.m.: 23 IR 1653; readopted filed Jun 22, 2001, 8:57 a.m.: 24 IR 3824; filed Apr 4, 2002, 9:28 a.m.: 25 IR 2519)*

SECTION 4. 872 IAC 1-1-10 IS AMENDED TO READ AS FOLLOWS:

872 IAC 1-1-10 Application; fees

Authority: IC 25-2.1-2-15
Affected: IC 4-21.5-3-1; IC 25-2.1

Sec. 10. (a) Applications to take the May examination must be filed by the preceding March 1. ~~Applications~~ **Application** to take the November examination must be filed by the preceding September 1. If March 1 or September 1 is a Saturday, a Sunday, a legal holiday under state statute, or a day that the Indiana professional licensing agency's offices are closed during regular business hours, the deadline shall be the first day thereafter that is not a Saturday, a Sunday, a legal holiday under state statute, or a day that the Indiana professional licensing agency's offices are closed during regular business hours. The date ~~an~~ **the** application is filed shall be calculated in the manner provided for in IC 4-21.5-3-1(f). Applicants will be notified of their eligibility to sit for the exam.

(b) All fees are nonrefundable and nontransferable. The following is a schedule of fees adopted by the board:

(1) Transfer of grades, forty dollars ($40).

(2) CPA certificate by reciprocity, fifty dollars ($50).

(3) Triennial certificate of registration for CPAs, PAs, and APs, forty-five dollars ($45).

(4) For restoration of an expired triennial certificate of registration for CPAs, PAs, and APs, fifty dollars ($50), plus all unpaid renewal fees.

~~(4)~~ **(5)** Triennial permit to practice for firms, twenty dollars ($20).

(6) For restoration of an expired triennial permit to practice for firms, fifty dollars ($50), plus all unpaid renewal fees.

(c) Notwithstanding subsection (b)(3), a fee for an individual initially registered in the:

(1) second year of a triennial registration period shall be thirty dollars ($30); and

(2) third year of the triennial registration period shall be fifteen dollars ($15).

(d) Failure of an applicant to pay the initial registration fee will cause the application to be terminated one (1) year after the board's action granting registration.

(e) Should an applicant pay the initial registration fee after the first renewal deadline for all licensees following the applicant's approval for licensure, the applicant must pay the renewal fee in addition to the initial registration fee in order to become licensed. *(Indiana Board of Accountancy; Rule 69-1, 10; filed Jun 30, 1978, 9:54 a.m.: 1 IR 396; filed Feb 15, 1980, 3:05 p.m.: 3 IR 639; filed Aug 18, 1983, 3:20 p.m.: 6 IR 1928; filed May 1, 1984, 12:50 p.m.: 7 IR 1540; filed Mar 20, 1985, 3:25 p.m.: 8 IR 1033; filed Aug 28, 1986, 3:20 p.m.: 10 IR 65; filed Aug 6, 1990, 4:30 p.m.: 13 IR 2135; filed Jun 1, 1994, 5:00 p.m.: 17 IR 2345; errata filed Jul 28, 1994, 4:00 p.m.: 17 IR 2891; filed Jul 6, 1995, 12:00 p.m.: 18 IR 2784; filed Jun 14, 1996, 3:00 p.m.: 19 IR 3110; filed Feb 21, 2000, 7:06 a.m.: 23 IR 1654; readopted filed Jun 22, 2001, 8:57 a.m.: 24 IR 3824; filed Apr 4, 2002, 9:28 a.m.: 25 IR 2520)*

SECTION 5. 872 IAC 1-1-8.1 IS REPEALED

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