sections, except for §13727 previously covered, are effective beginning with the reporting period ending December 31, 2010 and each year thereafter. An insurer or group of insurers that is not required to file a report because the total written premium is below the threshold and subsequently becomes subject to the reporting requirements shall have two years following the year the threshold is exceeded but not earlier than December 31, 2010 to file a report. Likewise, an insurer acquired in a business combination shall have two calendar years following the date of acquisition or combination to comply with the reporting requirements.

AUTHORITY NOTE: Promulgated in accordance with the R.S. 22:1 et seq., the "Audited Financial Reports Law" R.S. 22:671 et seq., more particularly R.S. 22:675 and the Administrative Procedure Act. R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner LR 35:2462 (November 2009).

§13735. Canadian and British Companies

A. In the case of Canadian and British insurers, the annual audited financial report shall be defined as the annual statement of total business on the form filed by such companies with their supervision authority duly audited by an independent chartered accountant.

B. For such insurers, the letter required in §13711.B shall state that the accountant is aware of the requirements relating to the annual audited financial report filed with the commissioner pursuant to §13707 and shall affirm that the opinion expressed is in conformity with those requirements.

AUTHORITY NOTE: Promulgated in accordance with the R.S. 22:1 et seq., the "Audited Financial Reports Law" R.S. 22:671 et seq., more particularly R.S. 22:675 and the Administrative Procedure Act. R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner LR 35:2462 (November 2009).

§13737. Severability Provision

A. If any Section or portion of a Section of Regulation 98 or its applicability to any person or circumstance is held invalid by a court, the remainder of the regulation or the applicability of the provision to other persons or circumstances shall not be affected.

AUTHORITY NOTE: Promulgated in accordance with the R.S. 22:1 et seq., the "Audited Financial Reports Law" R.S. 22:671 et seq., more particularly R.S. 22:675 and the Administrative Procedure Act. R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner LR 35:2462 (November 2009).

§13739. Effective Date

A. Regulation 98 shall become effective upon promulgation in the Louisiana Register.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:1 et seq., the "Audited Financial Reports Law" R.S. 22:671 et seq., more particularly R.S. 22:675 and the Administrative Procedure Act. R.S. 49:950 et seq.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner LR 35:2462 (November 2009).

Chapter 141. Regulation 100—Coverage of Prescription Drugs through a Drug Formulary

§14101. Purpose

A. The purpose of Regulation 100 is to implement Act 350 of the 2011 Regular Session of the Louisiana Legislature pertaining to the coverage of prescription drugs through a drug formulary as set forth in R.S. 22:1060.1 et seq. which provides for the continuation of drug coverage and notice to enrollees regarding drug formularies covered by a health insurance issuer as well as any modifications made thereto. The purpose of Regulation 100 is to clarify the requirements and notice forms now mandated by law.

B. The purpose of the amendment to Regulation 100 is to provide clarification set forth in R.S. 22:1068(F) and R.S. 22:1074(F) in regards to the requirement of obtaining approval from the commissioner whenever a health insurance issuer modifies health insurance coverage offered in the group and individual markets.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 1068(F) and R.S. 22:1074 (F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1027 (April 2012), amended LR 45:1207 (September 2019), repromulgated LR 45: 1778 (December 2019).

§14103. Authority

A. Regulation 100 is promulgated pursuant to the authority granted in R.S. 22:11, R.S. 22:1068F and R.S. 22:1074F.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1027 (April 2012).

§14105. Applicability and Scope

A. Regulation 100 applies to all health insurance issuers as well as health maintenance organizations as defined by R.S.22:1060.1(6).

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1027 (April 2012).

§14107. Definitions

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A. Definitions. As used in Regulation 100, the following terms shall have the meaning or definition as indicated herein.

Commissioner—commissioner of insurance for the state of Louisiana.

Enrollee—any individual, including a dependent, who is enrolled or insured by a health insurance issuer under a health benefit plan. *Policy Form*—an insurance contractual agreement delineating the terms, provisions and conditions of a particular insurance product. It includes certificates of coverage and any other evidence of coverage, subscriber agreements or application forms where written application is required and is to be attached to the policy or be a part of the contract, and any health and accident or health maintenance organization rider or endorsement form.

Particular Product—a basic insurance policy form delineating the terms, provisions and conditions of a specific type of coverage under a particular type of contract.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1027 (April 2012).

§14109. Required Notices

A. There shall be three different and distinct types of notice that a health insurance issuer is required to provide to every applicable enrollee. Each notice shall be filed with and approved by the Department of Insurance prior to use in Louisiana.

B. Notice and Disclosure of Drug Formulary Pursuant to R.S. 22:1060.2(A)(1)(e). A health insurance issuer shall file a "Notice and Disclosure of Drug Formulary" form with the Department of Insurance as a part of its coverage documentation. The "Notice and Disclosure of Drug Formulary" shall contain all of the information enumerated in R.S. 22:1060.2. A health insurance issuer shall submit this form for approval by the commissioner. Once the form is approved by the commissioner, the health insurance issuer shall only utilize said form. A health insurance issuer shall maintain written evidence such as a record, report or data compilation of enrollees who request disclosure or information about any specific drug that is included in a formulary. The written evidence such as a record, report, or data compilation shall include the name of the enrollee, the date of request, the date of response by the health insurance issuer and the specific drug requested. A health insurance issuer shall provide a copy of the written evidence such as a record, report or data compilation as described herein to the commissioner within 15 days of written request by the commissioner.

C. Notice that Enrollee Has Right to Continuation of Coverage Pursuant to R.S. 22:1060.3. A health insurance issuer shall notify an enrollee as a part of coverage documentation that the enrollee shall have the right to continue the coverage of any prescription drug that was approved or covered by the health insurance issuer, and that the coverage of such prescription drug shall be at the contracted benefit level until the renewal of the enrollee's current plan. A health insurance issuer shall maintain written evidence such as a record, report or data compilation of enrollees who request continuation of coverage and the name of the specific drug. The written evidence such as a record, report, or data compilation shall include the name of the enrollee, the date of request, the date of response by the health insurance issuer and the name of the specific drug requested. A health insurance issuer shall provide a copy of the written evidence such as a record, report or data compilation as described herein to the commissioner within 15 days of written request by the commissioner.

D. Notice of Modification-Group Market Pursuant to R.S. 22:1068(D)(3) and Individual Market Pursuant to R.S. 22:1074(D)(3). A "Notice of Modification of Benefit Coverage or Drug Coverage of a Particular Product" form is required to contain the information required in R.S. 22:1068(D)(3) and 22:1074(D)(3). Such form used by a health insurance issuer shall be approved by the commissioner and no form may be used until approved by the commissioner. For group policies, such notice shall be delivered to the affected covered small group or large group employer and all enrollees at the last known address no later than the sixtieth day before any modification of benefit coverage or drug coverage of a particular product is to become effective. For individual policies, such notice shall be delivered to each affected individual at the last known address no later than the sixtieth day before any modification of benefit coverage or drug coverage of a particular product is to become effective.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1027 (April 2012).

§14111. Requirements for the Modification Affecting Drug Coverage

A. A modification affecting drug coverage shall mean any of the following:

1. removing a drug from a formulary;

2. adding a requirement that an enrollee receive prior authorization for a drug;

3. imposing or altering a quantity limit for a drug;

4. imposing a step-therapy restriction for a drug;

5. moving a drug to a higher cost-sharing tier, unless a generic alternative is available.

B. A health insurance issuer shall notify the commissioner in writing of a modification affecting drug coverage 75 days prior to the renewal date of the policy form as to those modifications enumerated in R.S. 22:1061(5) and set forth in § 14111.A herein. A health insurance issuer shall provide the notice of modification affecting drug coverage as provided for in R.S. 22:1068(D)(3) and R.S. 22:1074(D)(3) and shall only modify the policy or contract of insurance at the renewal of the policy or contract of insurance.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1028 (April 2012), amended LR 45:1207 (September 2019), repromulgated LR 45: 1778 (December 2019).

§14113. Enrollee's Right to Appeal Adverse Determination

A. The refusal of a health insurance issuer to provide benefits to an enrollee for a prescription drug is an adverse determination for the purposes of Subpart F of Part III of Chapter 4 of the Louisiana Insurance Code, R.S. 22:1121 et seq., relative to medical necessity review organizations, if each of the following conditions is met.

1. The drug is not included in a drug formulary used by the health benefit plan.

2. The enrollee's physician or other authorized prescriber has determined the drug is medically necessary.

B. An enrollee may appeal the adverse determination pursuant to subpart F of part III of chapter 4 of the Louisiana Insurance Code, R.S. 22:1121 et seq., relative to medical necessity review organizations.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1028 (April 2012).

§14115. Requirements for Modifying a Group Insurance Product

A. Pursuant to R.S. 22:1068, a health insurance issuer may modify its drug coverage offered to a group health plan if each of the following conditions is met.

1. The modification occurs at the time of coverage renewal.

2. The modification is approved by the commissioner. However, modification affecting drug coverage as defined in R.S. 22:1061(5)(y) and found in §14111.A. of this regulation shall not require approval by the commissioner.

3. The modification is consistent with state law.

4. The modification is effective on a uniform basis among all small or large employers covered by that group health plan.

5. The health insurance issuer, on the form approved by the Department of Insurance, notifies the small or large employer group and each enrollee therein of the modification no later than the sixtieth day before the date the modification is to become effective.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1028 (April 2012), amended LR 45:1207 (September 2019), repromulgated LR 45: 1778 (December 2019).

§14117. Requirements for Modifying an Individual Insurance Product

A. Pursuant to R.S. 22:1074, a health insurance issuer may modify its drug coverage offered to individuals if each of the following conditions is met.

1. The modification occurs at the time of coverage renewal.

2. The modification is approved by the commissioner. However, modification affecting drug coverage as defined in R.S. 22:1061(5)(y) and found in §14111.A. of this regulation shall not require approval by the commissioner.

3. The modification is consistent with state law.

4. The modification is effective on a uniform basis among all individuals with that policy form.

5. The health insurance issuer, on a form approved by the Department of Insurance, notifies each affected individual of the modification no later than the sixtieth day before the date the modification is to become effective.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1028 (April 2012), amended LR 45:1207 (September 2019), repromulgated LR 45:1779 (December 2019).

§14119. Modification Affecting Drug Coverage

A. To facilitate the ability of the commissioner to comply with his statutory duty, the commissioner shall have the authority to enter into a contract with any person or entity he deems applicable, relevant and/or appropriate to provide advice and/or make a recommendation to the commissioner.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22: 1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 38:1028 (April 2012), amended 45:1207 (September 2019) , repromulgated LR 45: 1779 (December 2019).

§14120. Effective Date

A. This regulation shall be effective upon final publication in the *Louisiana Register*.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11, R.S. 22:1068(F) and R.S. 22:1074(F).

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 45:1208 (September 2019), repromulgated LR 45: 1779 (December 2019).

Chapter 143. Regulation 101—Registration and Regulation of Navigators

§14301. Purpose

A. The purpose of Regulation 101 is to implement a provision of Act 349 of the 2013 Regular Session of the Louisiana Legislature relative to the registration and regulation of navigators as authorized in R.S. 22:753.

AUTHORITY NOTE: Promulgated in accordance with R.S. 22:11 and 22:753.

HISTORICAL NOTE: Promulgated by the Department of Insurance, Office of the Commissioner, LR 39:2774 (October 2013).

§14303. Authority

A. Regulation 101 is promulgated pursuant to the authority granted in R.S. 22:11 and 22:753(H)(5).