

DEPARTMENT OF INSURANCE

OFFICE OF THE COMMISSIONER

Statutory Authority: 18 Delaware Code, Sections 332, 6408, 6416 and 6417 (18 **Del.C.** §§332, 6408, 6416 & 6417)

18 **DE Admin. Code** 1301

FINAL

REGULATORY IMPLEMENTING ORDER

1301 Internal Review and Independent Utilization Review of Health Insurance Claims

I. SUMMARY OF THE EVIDENCE AND INFORMATION SUBMITTED

At 21 **DE Reg.** 192 (September 1, 2017), the Department published its first notice of intent to amend Regulation 1301 and solicited written comments from the public for thirty (30) days as mandated by 29 **Del.C.** §10118(a). The Department's docket number is DOI Docket No. 3571-2017.

In its first notice, the Department proposed to amend the definition of "Authorized Representative" and the content of the notice to be provided by insurance carriers to their insureds. These proposed amendments implement Section 3 of HB 100, which amended 18 **Del.C.** §332 to now require that an insurance carrier, when informing a covered person of its internal review process, must inform the covered person of the availability of assistance from the Delaware Department of Justice (DOJ) in the preparation of an appeal of an adverse determination involving treatment for substance abuse.

HB 100 was signed into law on May 30, 2017, became effective on September 27, 2017 and sunsets on January 1, 2020 unless expressly reauthorized prior to that date. The Department also proposed non-substantive amendments to correct punctuation at subsections 3.1.6 and 9.4.6, and to correct style throughout subsections 5.7, 7.1 and 11.1, and throughout Sections 9.0 and 10.0.

The Governor's Advisory Council for Exceptional Citizens and the State Council for Persons with Disabilities submitted an identical set of comments on the substance of the amendments proposed in September. Both organizations offered their support of the proposed amendments, and suggested that the Department more clearly ensure that the regulations clearly state that assistance from the DOJ is available at all stages of the appeals process for cases involving substance abuse.

In response to the comments received, the Department gave notice in the Delaware *Register of Regulations* at 21 **DE Reg.** 400 (11/01/17) of the re-proposal of amendments to Regulation 1301 with additional amendments that incorporate commenters' suggestions. The re-proposal of amendments to companion Regulation 1315 were published at 21 **DE Reg.** 406 (11/01/17).

The Department did not hold a public hearing on the re-proposal. The Department accepted written comments, suggestions, briefs, and compilations of data or other materials concerning the re-proposal of amendments until the 4:30 p.m. EST, the 4th day, December, 2017, which was thirty days from the date of publication.

The Governor's Advisory Council for Exceptional Citizens and the State Council for Persons with Disabilities again submitted an identical set of comments on the substance of the amendments proposed in November, this time endorsing the amendments without qualification. A copy of those comments are available by contacting the Department.

II. FINDINGS OF FACTS

The Commissioner finds that it is appropriate to adopt proposed amendments to 18 **DE Admin. Code** 1301 as proposed. The Department received no adverse comments on the amendments as re-proposed and the amendments as re-proposed appropriately implement Section 3 of HB 100. See elsewhere in this issue of the Delaware *Register of Regulations* for the adoption of amendment to companion Regulation 1315.

III. DECISION TO AMEND THE REGULATION

For the foregoing reasons, the Commissioner concludes that it is appropriate to amend 18 **DE Admin. Code** 1301 as re-proposed.

V. EFFECTIVE DATE OF ORDER

The actions hereinabove referred to were taken by the Commissioner pursuant to 18 Delaware Code, Sections 332, 6408, 6416 and 6417 on December 15, 2017. The effective date of this Order shall be ten (10) days from the date this Order is published in the Delaware *Register of Regulations*.

IT IS SO ORDERED.

The 15th day of December, 2017
Trinidad Navarro, Commissioner

1301 Internal Review and Independent Utilization Review of Health Insurance Claims

1.0 Purpose and Statutory Authority

The purpose of this Regulation is to implement 18 **Del.C.** §§332, 6408, 6416 and 6417 which require health insurance carriers to establish a procedure for internal review of a carrier's adverse coverage determination and which require the Delaware Insurance Department to establish and administer procedures for independent utilization review upon completion of the carrier's internal review process. This Regulation is promulgated pursuant to 18 **Del.C.** §§311, 332, 6408, 6416, and 6417 and 29 **Del.C.** Ch. 101. This Regulation should not be construed to create any cause of action not otherwise existing at law.

19 DE Reg. 923 (04/01/16)

2.0 Definitions

2.1 The following words and terms, when used in this regulation, should have the following meaning unless the context clearly indicates otherwise:

"Adverse determination" means a decision by a carrier to deny (in whole or in part), reduce, limit or terminate health insurance benefits or a determination that an admission or continued stay, or course of treatment, or other covered health service does not satisfy the insurance policy's clinical requirements for appropriateness, necessity, health care setting and/or level of care.

"Appeal" means a request for external review of a carrier's final coverage decision through the Independent Health Care Appeals Program.

"Appropriateness of services" means an appeal classification for adverse determinations that are made based on identification of treatment as cosmetic, investigational, experimental or not an appropriate or preferred treatment method or setting for the condition for which treatment is sought.

"Authorized representative" means an individual ~~who~~ whom a covered person willingly acknowledges to represent his interests during the internal review process and/or an appeal through the arbitration process or the Independent Health Care Appeals Program, including but not limited to a provider to whom a covered person has assigned the right to collect sums due from a carrier for health care services rendered by the provider to the covered person. A carrier may require the covered person to submit written verification of his consent to be represented. If a covered person has been determined by a physician to be incapable of assigning the right of representation, the covered person may be represented by a family member or a legal representative. In cases involving the existence or scope of private or public coverage for substance abuse treatment, assistance may be provided by or through the Delaware Department of Justice as an authorized representative, regardless of whether the covered person has been determined by a physician to be incapable of assigning the right of representation. The Department of Justice may be reached by calling 302-577-4206, by visiting <http://attorneygeneral.delaware.gov/dojreatmentassistance/>, or by email at dojreatmentassistance@state.de.us.

"Carrier" means any entity that provides health insurance in this State. Carrier includes an insurance company, health service corporation, managed care organization and any other entity providing a plan of health insurance or health benefits subject to state insurance regulation. Carrier also includes any third-party administrator or other entity that adjusts, administers or settles claims in connection with health insurance.

"Covered person" means an individual and/or family who has entered into a contractual arrangement, or on whose behalf a contractual arrangement has been entered into, with a carrier, pursuant to which the carrier provides health insurance for such person or persons.

"Department" means the Delaware Insurance Department.

"Final coverage decision" means the decision by a carrier at the conclusion of its internal review process upholding, modifying or reversing its adverse determination.

"Grievance" means a request by a covered person or his authorized representative that a carrier review an adverse determination by means of the carrier's internal review process.

"Health care services" means any services or supplies included in the furnishing to any individual of medical care, or hospitalization or incidental to the furnishing of such care or hospitalization, as well as the furnishing to any individual of any and all other services for the purpose of preventing, alleviating, curing or healing human illness, injury, disability or disease.

"Health insurance" means a plan or policy issued by a carrier for the payment for, provision of, or reimbursement for health care services.

"Independent Health Care Appeals Program ("IHCAP") means a program administered by the Department that provides for an external review by an Independent Utilization Review Organization of a carrier's final coverage decision based on medical necessity or appropriateness of services.

"Independent Utilization Review Organization ("IURO") means an entity that conducts independent external reviews of a carrier's final coverage decisions resulting in a denial, termination, or other limitation of covered health care services based on medical necessity or appropriateness of services.

"Internal review process ("IRP") means a procedure established by a carrier for internal review of an adverse determination.

"Medical necessity" means providing of health care services or products that a prudent physician would provide to a patient for the purpose of diagnosing or treating an illness, injury, disease or its symptoms in a manner that is:

- A. In accordance with generally accepted standards of medical practice;
- B. Consistent with the symptoms or treatment of the condition; and
- C. Not solely for anyone's convenience.

"Pre-Authorization" is a requirement by a carrier or health insurance plan that states physicians need to submit a treatment plan or service request to the carrier for evaluation of appropriateness of the plan or service before treatment is rendered. It lets the insured and physician know in advance which procedures are covered.

"Provider" means an individual or entity, including without limitation, a licensed physician, a licensed nurse, a licensed physician assistant and a licensed nurse practitioner, a licensed diagnostic facility, a licensed clinical facility, and a licensed hospital, who or which provides health care services in this State.

12 DE Reg. 974 (01/01/09)

19 DE Reg. 923 (04/01/16)

3.0 Minimum Requirements for an Internal Review Process (IRP)

3.1 In addition to the requirements set forth in 18 Del.C. §332, the following provisions of this section shall govern the internal review process of all carriers offering health insurance in Delaware:

3.1.3.2 All written procedures and forms utilized by a carrier shall be readable and understandable by a person of average intelligence and education. All such documents shall meet the following criteria:

3.1.13.2.1 The type size shall not be smaller than 11 point;

3.1.23.2.2 The type style selection shall be at the discretion of the carrier but shall be of a type that is clear and legible;

3.1.33.2.3 Captions or headings shall be designed to stand out clearly;

3.1.43.2.4 White space separating subjects or sections should be distinct;

3.1.53.2.5 There must be included a table of contents sufficient to guide and assist the covered person or his authorized representative;

3.1.63.2.6 Where appropriate, definitions shall be included, shall be sufficient to clearly apply to the usage intended, and shall not conflict with the definitions contained in this regulation; and

3.1.73.2.7 The forms shall be written in everyday, conversational language to the extent possible to preserve the legal meaning.

3.1.83.2.8 Short familiar words shall be used and sentences shall be kept as short and simple as possible.

3.23.3 The carrier shall provide all forms relating to grievances, appeals, arbitration or other procedures relating to IRP as examples along with the written notice of IRP provided to the covered person.

3.33.4 Written notice.

3.3.13.4.1 For any IRP not previously approved by the Department, the carrier shall provide written notice of the IRP to all covered persons within 30 days of approval by the Department.

3.3.23.4.2 The carrier shall provide the notice required by 18 Del.C. §332(c)(1) to covered persons following any adverse determination, and annually, either upon the policy renewal date, open enrollment date, or a set date for all covered persons, in the carrier's discretion. In addition to the requirements set forth in 18 Del.C. §332(c)(1), the notice shall also, at a minimum, provide as follows:

3.4.2.1 You have the right to seek a review of a claim reduction or denial through this insurer's internal review process.

3.4.2.2 If your claim involves an adverse determination involving treatment for substance abuse, you may be eligible to receive assistance by or through the Delaware Department of Justice during this company's internal review process. The Delaware Department of Justice may be reached by

calling 302-577-4206, by visiting <http://attorneygeneral.delaware.gov/dojreatmentassistance/>, or by email at dojreatmentassistance@state.de.us, for more information.

~~3.3.33.4.3~~ For every new policy issued after the Department's approval of the IRP, the carrier shall provide covered persons with a copy of the IRP at the time, or prior to the time, the carrier sends identification cards, member handbooks or similar member materials to newly covered persons.

~~3.3.43.4.4~~ When a covered person's dependents are also covered, a single notice to the principal covered person shall be sufficient under this section.

~~3.43.5~~ Under circumstances where an oral or written grievance may not contain sufficient information and the carrier requests additional information, such request shall not be burdensome or require such information as the carrier might reasonably be expected to obtain through its normal claims process.

4.0 Mediation Services Notice Requirements for Appeal of a Carrier's Final Coverage Decision

At the time a carrier provides to a covered person written notice of a carrier's final coverage decision, if the final coverage decision does not authorize payment of the claim in its entirety, the carrier shall provide the covered person with a written notice of the process by which a covered person may appeal the carrier's final coverage decision. The notice shall include a statement that mediation services are offered by the Department. Such notice may be separate from or a part of the written notice of the carrier's decision.

~~Any~~ The notice provided to a covered person shall, at a minimum, contain the following language:

"You have the right to seek a review of a claim reduction or denial through the Delaware Insurance Department. The Delaware Insurance Department ~~also~~ provides free informal mediation services which are in addition to, but do not replace, your right to a review of this decision through an external review or through the Department's arbitration program, as applicable. You can contact the Delaware Insurance Department for information about claim denial review or mediation by calling the Consumer Services Division at 800-282-8611 or ~~302-739-4254~~ 302-674-7310.

Your decision to pursue mediation with the Department does not change the deadlines imposed for filing a request for an external review (set by Section 5.0 of this regulation) or arbitration (set by Regulation 1315 of Delaware Administrative Code Chapter 18, 18 DE Admin. Code 1315).

If your request for review involves a claim reduction or denial involving treatment for substance abuse, you may be eligible to receive assistance by or through the Delaware Department of Justice by calling 302-577-4206, by visiting <http://attorneygeneral.delaware.gov/dojreatmentassistance/>, or by email at dojreatmentassistance@state.de.us for more information.

All requests for review through ~~procedures established by the Delaware Insurance Department~~ the Department's arbitration program must be filed with the Department within 60 days from the date you receive this carrier's notice; otherwise, this decision will be final. All requests for external review must be filed with this carrier within four months of your receipt of this final coverage decision."

19 DE Reg. 923 (04/01/16)

5.0 IHCAP Procedure

5.1 A covered person or his authorized representative may request review of a final coverage decision based, in whole or in part, on medical necessity or appropriateness of services by filing an appeal with the carrier within four months of receipt of the final coverage decision.

5.2 Upon receipt of an appeal, the carrier shall transmit the appeal electronically to the Department as soon as possible, but within no more than three business days.

5.3 Within five calendar days of receipt of an appeal, the Department shall assign an approved, impartial Independent Utilization Review Organization to review the final coverage decision and shall notify the carrier.

5.4 The assigned IURO shall, within five calendar days of assignment, notify the covered person or his authorized representative in writing by certified or registered mail that the appeal has been accepted for external review.

5.4.1 The notice shall include a provision stating that the covered person or his authorized representative may submit additional written information and supporting documentation that the IURO shall consider when conducting the external review.

5.4.2 The covered person or his authorized representative shall submit such written documentation to the IURO within seven calendar days following the date of receipt of the notice.

- 5.4.3 Upon receipt of any information submitted by the covered person or his authorized representative, the assigned IURO shall as soon as possible, but within no more than two business days, forward the information to the carrier.
- 5.4.4 The IURO must accept additional documentation submitted by the carrier in response to additional written information and supporting documentation from the covered person or his authorized representative.
- 5.5 Within seven calendar days after the receipt of the notification required in subsection 5.3, the carrier shall provide to the assigned IURO the documents and any information considered in making the final coverage decision.
 - 5.5.1 If the carrier fails to submit documentation and information or fails to participate within the time specified, the assigned IURO may terminate the external review and make a decision, with the approval of the Department, to reverse the final coverage decision.
- 5.6 The external review may be terminated if the carrier decides to reverse its final coverage decision and provide coverage or payment for the health care service that is the subject of the appeal.
 - 5.6.1 Immediately upon making the decision to reverse its final coverage decision, the carrier shall notify the covered person or his authorized representative, the assigned IURO, and the Department in writing of its decision. The assigned IURO shall terminate the external review upon receipt of the written notice from the carrier.
- 5.7 Within 45 days after the IURO's receipt of an appeal, the assigned IURO shall provide written notice of its decision to uphold or reverse the final coverage decision to the covered person or his authorized representative, the carrier and the Department, which notice shall include the following information:
 - 5.7.1 ~~the~~ The qualifications of the members of the review panel;
 - 5.7.2 ~~a~~ A general description of the reason for the request for external review;
 - 5.7.3 ~~the~~ The date the IURO received the assignment from the Department to conduct the external review;
 - 5.7.4 ~~the~~ The date(s) the external review was conducted;
 - 5.7.5 ~~the~~ The date of its decision;
 - 5.7.6 ~~the~~ The principal reason(s) for its decision; and
 - 5.7.7 ~~references~~ References to the evidence or documentation, including practice guidelines and clinical review criteria, considered in reaching its decision.
- 5.8 The decision of the IURO is binding upon the carrier except as provided in 18 **Del.C.** §6416(b).

19 DE Reg. 923 (04/01/16)

6.0 Expedited IHCAP Procedure

- 6.1 A covered person or his authorized representative may request an expedited appeal at the time the carrier issues its final coverage decision if the covered person suffers from a condition that poses an imminent, emergent or serious threat or has an emergency medical condition.
 - 6.1.1 For an emergency medical condition, the claimant may file for an external review without having already exhausted the internal appeal process. To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the carrier (or, if applicable, the plan) has waived the requirement, the carrier (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in 45 CFR 147.136(b)(2) and (3)), or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.
- 6.2 At the time the carrier receives a request for an expedited appeal, the carrier shall immediately transmit the appeal electronically to the Department, but within no more than three business days.
- 6.3 If the Department determines that the review meets the criteria for expedited review, the Department shall assign an approved, impartial IURO to conduct the external review and shall notify the carrier.
- 6.4 At the time the carrier receives the notification of the assigned IURO, the carrier shall provide or transmit all necessary documents and information considered in making its final coverage decision to the assigned IURO electronically, by telephone, by facsimile or any other available expeditious method.
- 6.5 As expeditiously as the covered person's medical condition permits or circumstances require, but in no event more than 72 hours after the IURO's receipt of the expedited appeal, the IURO shall make a decision to uphold or reverse the final coverage decision and immediately notify the covered person or his authorized representative, the carrier, and the Department of the decision.
- 6.6 Within one calendar day of the immediate notification, the assigned IURO shall provide written confirmation of its decision to the covered person or his authorized representative, the carrier, and the Department.
- 6.7 The decision of the IURO is binding upon the carrier except as provided in 18 **Del.C.** §6416(b).

19 DE Reg. 923 (04/01/16)

7.0 Refusal or Dismissal of IHCAP Appeal

- 7.1 The Department may refuse to accept any appeal that is not timely filed or does not otherwise meet the criteria for IHCAP review. If the subject of the appeal is appropriate for arbitration, the Department shall advise the covered person or his authorized representative of the arbitration procedure. If the subject of the appeal is appropriate for arbitration, the appeal shall be treated as a petition for arbitration.
- 7.2 Carrier's motion to dismiss an IHCAP appeal.
- 7.2.1 A carrier may move to dismiss an IHCAP appeal if the carrier believes the appeal:
- 7.2.1.1 ~~the appeal concerns~~ Concerns a benefit that is the subject of an express written exclusion from the covered person's health insurance;
- 7.2.1.2 ~~the appeal is~~ Is appropriate for arbitration; or
- 7.2.1.3 ~~the appeal should~~ Should be dismissed because it is inappropriate for IHCAP review as explained in a sworn statement by an officer of the carrier.
- 7.2.2 The carrier's motion to dismiss must be made in writing at the time the carrier transmits the appeal to the Department and must include any necessary supporting documentation.
- 7.2.3 The Department shall review the appeal and motion for dismissal and may, in its discretion:
- 7.2.3.1 ~~dismiss~~ Dismiss the appeal and notify the covered person or his authorized representative in writing that the appeal is inappropriate for the IHCAP; or
- 7.2.3.2 ~~appoint~~ Appoint an IURO to conduct a full external review.

19 DE Reg. 923 (04/01/16)

8.0 IHCAP Costs

- 8.1 All costs for IHCAP review by an IURO, whether the review is preliminary, or partially or fully completed, shall be borne by the carrier.
- 8.1.1 These costs shall include a \$75.00 administration fee for processing and handling by the Department.
- 8.2 The carrier shall reimburse the Department for the cost of the IHCAP review within 90 calendar days of receipt of the decision by the IURO or within 90 days of termination of review by the IURO by other means.

19 DE Reg. 923 (04/01/16)

9.0 Approval of Independent Utilization Review Organizations

- 9.1 The Department shall approve IUROs eligible to be assigned to conduct IHCAP reviews as provided in 18 **Del.C.** §6417(a).
- 9.2 An IURO seeking approval to conduct IHCAP reviews shall submit an application to the Department that includes the information required by 18 **Del.C.** §§6417(c)(1), 6417(c)(2), 6417(c)(4), and a copy of its certification by URAC or other nationally recognized certification organization.
- 9.3 The Department shall maintain a current list of approved IUROs.
- 9.4 In connection with each external review, neither the expert reviewer, nor the independent review organization, shall have any material professional, familial or financial conflict of interest with any of the following:
- 9.4.1 The plan;_
- 9.4.2 Any officer, director or management of the plan;_
- 9.4.3 The physician, the physician's medical group or the independent practice association proposing the service or treatment;_
- 9.4.4 The institution at which the service or treatment would be provided;_
- 9.4.5 The development or manufacture of the principal drug, device, procedure or other therapy proposed for the covered person whose treatment is under review;_
- 9.4.6 The covered person;_ or
- 9.4.7 ~~National~~ Any national, state or local trade association of health benefit plans or health-care providers.

19 DE Reg. 923 (04/01/16)

10.0 Recordkeeping and Reporting Requirements

- 10.1 A carrier and IURO shall maintain written or electronic records for five years, after completion of the appeal process, documenting all grievances and appeals for IHCAP review including, at a minimum, the following information:

10.1.1 For each grievance:

10.1.1.1 ~~the~~ The date received;

10.1.1.2 ~~name~~ Name and plan identification number of the covered person on whose behalf the grievance was filed;

10.1.1.3 ~~a~~ A general description of the reason for the grievance; and

10.1.1.4 ~~the~~ The date and description of the final coverage decision.

10.1.2 For each appeal for IHCAP review:

10.1.2.1 ~~the~~ The date received;

10.1.2.2 ~~name~~ Name and plan identification number of the covered person on whose behalf the appeal was filed;

10.1.2.3 ~~a~~ A general description of the reason for the appeal; and

10.1.2.4 ~~date~~ Date and description of the IURO's decision or other disposition of the appeal.

10.2 A carrier shall file with its annual report to the Department the following information:

10.2.1 The total number grievances filed; ~~and~~

10.2.2 The total number of IHCAP appeals filed, with a breakdown showing the total number of final coverage decisions:

10.2.2.1 ~~the total number of final coverage decisions upheld~~ Upheld through IHCAP; and

10.2.2.2 ~~the total number of final coverage decisions reversed~~ Reversed through IHCAP.

10.3 A carrier shall make available to the Department upon request any of the information specified in the foregoing subsections 10.1 and 10.2, and other information regarding its internal review process including but not limited to the written IRP procedures and forms the carrier distributes to covered persons.

10.4 An IURO shall make available to the Department upon request any of the information specified in the foregoing subsections 10.1 and 10.2 to the extent within the IURO's records.

19 DE Reg. 923 (04/01/16)

11.0 Non-Retaliation

11.1 A carrier shall not disenroll, terminate or in any way penalize a covered person who exercises his or her rights to file a grievance or appeal for IHCAP review solely on the basis of such filing.

11.2 A carrier shall not terminate or in any way penalize a provider with whom it has a contractual relationship and who exercises, on behalf of a covered person, the right to file a grievance or appeal for IHCAP review solely on the basis of such filing.

19 DE Reg. 923 (04/01/16)

12.0 Confidentiality of Health Information

Nothing in this Regulation shall supersede any federal or state law or regulation governing the privacy of health information.

19 DE Reg. 923 (04/01/16)

13.0 Computation of Time

In computing any period of time prescribed or allowed by this Regulation, the day of the act or event after which the designated period of time begins to run shall not be included. The last day of the period so computed shall be included, unless it is a Saturday or Sunday, or other legal holiday, or other day on which the Department is closed, in which event the period shall run until the end of the next day on which the Department is open. When the period of time prescribed or allowed is less than 11 days, intermediate Saturdays, Sundays, and other legal holidays shall be excluded in the computation. As used in this section, "legal holidays" shall be those days provided by statute or appointed by the Governor or the Chief Justice of the State of Delaware.

14.0 Effective Date

This regulation shall become effective 10 days after being published as a final regulation. The amendments to Sections 3.0 and 4.0 of this regulation and to the definition of "Authorized representative," all of which implement HB 100, 81 Del. Laws, Ch. 28 §3 (May 30, 2017) shall become effective 10 days after being published as a final regulation and shall sunset on January 1, 2020 unless expressly reauthorized prior to that date.

11 DE Reg. 68 (07/01/07)

12 DE Reg. 974 (01/01/09)

19 DE Reg. 923 (04/01/16)

21 DE Reg. 580 (01/01/18) (Final)