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ACT SUMMARY

- Consolidates the process of disputing a denied benefit claim and submitting the claim for external review under one chapter and makes conforming changes to bring Ohio law into compliance with federal law and regulations related to external reviews.
- Expands the definition of adverse determination to encompass a larger class of claim denials, including the imposition of exclusions, decisions not to issue health insurance, and decisions to rescind coverage.
- Expands the express requirement for health issuers to have an internal appeal process from health insuring corporations only to also include sickness and accident insurers and public employee benefit plans.
- Permits an independent review organization to reverse an adverse benefit determination if the health plan issuer does not timely provide specified information.
- Stipulates that the new processes and requirements related to external reviews are effective for those adverse benefit determinations provided on or after January 1, 2012.

- Increases the situations under which health plan issuers must provide notifications to covered individuals and specifies what must be included in these notifications.
- Authorizes de minimis violation of the 30-day, internal appeal exhaustion deadline if it can be demonstrated that the violation does no serious harm to the covered person and is part of ongoing, good faith communications between the covered person and the health plan issuer.
- Prohibits health plan issuers offering individual health insurance coverage from requiring more than one level of internal review before an external review may be requested.
- Specifies that independent review organizations are not bound by any conclusions reached by the health plan issuer during a utilization review or an internal appeal.
- Enables non-terminal cases involving an experimental or investigational review to be eligible for external review.
- Requires health plan issuers to record data related to requests for external reviews and to report this information to the Superintendent of Insurance upon request.
- Specifies that health plan issuers are required to pay for the costs of an external review, including any secondary external reviews initiated by the Superintendent of Insurance.
- Reduces the time in which an independent review organization must make a decision on an expedited review from seven days to 72 hours.
- Removes the external review cost threshold of \$500, enabling claims to be eligible for external review, regardless of cost.
- Requires health insurers providing prescription drug benefits to utilize the standard medical reference compendia adopted by the United States Department of Health and Human Services when determining if a drug is safe and effective for treatment of an indication.

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CONTENT AND OPERATION

Overview

The act consolidates the process of disputing a denied benefit claim for external review under one chapter and makes conforming changes to bring Ohio law in compliance with federal law and regulations related to external reviews. The act also requires health insurers providing prescription drug benefits to utilize the standard medical reference compendia adopted by the United States Department of Health and Human Services when determining if a drug is safe and effective for treatment of an indication.

Consolidation

The act consolidates the external review process under a single chapter of law. Under prior law, this process was spread across several sections with separate, but largely identical, procedures being prescribed for health insuring corporations, sickness and accident insurers, and public employee benefit plans. Furthermore, for each of these types of insurers, the law prescribed three separate external review procedures: one for standard reviews, one for external reviews involving a terminal case, and one for contractual reviews with the Superintendent of Insurance (Superintendent). The act standardizes, for all types of insurers, four types of external reviews: (1) a standard review, (2) an expedited review, (3) a review involving an experimental treatment, and (4) a contractual review with the Superintendent. Under the act, the Superintendent is also responsible for providing an additional level of review for those claims involving emergency medical services that have been denied as being medically unnecessary through both an internal appeal and external review.¹

In the interest of brevity, this analysis uses vocabulary similar to that which is used under the act. "Health plan issuer" means a health insuring corporation, a sickness and accident insurer, and a public employee health plan. "Covered person" refers to any individual that is provided with health insurance under any of the aforementioned plans.

Standard external review – prior law

The following is an overview of the external review process as it existed under prior law.

¹ R.C. 1751.83 to 1751.88, 3923.66 to 3923.70, and 3923.75 to 3923.79.

Eligibility

Former law required that health plan issuers afford covered individuals an opportunity for an external review of a coverage denial if both of the following were met:

- The plan had denied coverage for what would otherwise have been a covered service, except that the health plan issuer had determined the service was not medically necessary;
- The proposed service, if not covered by the plan, would have cost more than \$500, except when an expedited review was requested.²

Additionally, an enrollee was not required to be afforded an external review if any of the following were met:

- The Superintendent had determined that the requested service was not covered under the covered person's health benefit plan;
- The covered person had failed to exhaust the health plan issuer's internal review process;
- The covered person had previously been afforded an external review for the same adverse determination;
- The request for an external review was made later than 180 days after the notice of a denial pursuant to an internal appeal.³

Requests for external reviews

An external review could have been requested by the covered person, the health service provider, or the facility. Except in the case of an expedited review, an external review must have been requested in writing and accompanied by written certification from the covered person's provider that the cost of the requested service would have been more than \$500.⁴

² R.C. 1751.84(A)(1) and (A)(2), 3923.67(A)(1) and (A)(2), and 3923.76(A)(1) and (A)(2) (repealed by the act).

³ R.C. 1751.84(B) and (C), 3923.67(B) and (C), and 3923.76(B) and (C) (repealed by the act).

⁴ R.C. 1751.84(C), 3923.67(C), and 3923.76(C) (repealed by the act).

Expedited review

To qualify for an expedited review, the covered person's provider must have certified that delay of the requested treatment could have resulted in any of the following:

- Placing the health of the insured in serious jeopardy;
- Serious impairment to bodily functions;
- Serious dysfunction of any bodily organ or part.⁵

Procedures for external review

The review was required to be conducted by an independent review organization assigned by the Superintendent. Clinical peers conducting external reviews were prohibited from having a relationship that posed a conflict of interest. Covered individuals were not required to pay for any part of an external review.

Health plan issuers were required to provide the independent organization with all relevant medical information, as well as any additional, necessary information. An independent review organization was not required to make a determination if such information was not provided, and was required to provide notice to the health plan issuer and the covered person in such situations. Prior law prescribed that the covered person's medical records, relevant criteria, findings and other scientific evidence, must be considered. Health plan issuers were required to provide coverage, should an external review overturn an adverse benefit determination.⁶

Terminal review – overview of prior law

Former law allowed for an external review of a claim involving an experimental or investigational treatment only in those situations where the covered person had a terminal illness. Among other criteria, the law required that other, standard therapies be ineffective or medically inappropriate, and that the requested service be a service that would be covered if it were not experimental or investigational.

Such experimental reviews were to be conducted by a clinical panel of three expert physicians with at least three years of experience in the relevant field. Prior law prescribed that such panels consider various criteria, including findings, studies, and other scientific research related to the adverse benefit determination. Each expert on

⁵ R.C. 1751.84(C)(3), 3923.67(C)(3), and 3923.76(C)(3) (repealed by the act).

⁶ R.C. 1751.84, 3923.67, and 3923.76 (repealed by the act).

the panel was required to provide an opinion on the adverse benefit determination. The health plan issuer was bound by the majority of the opinions of the clinical experts.⁷

External reviews as prescribed by the act

Definitions

The act expands several definitions to accomplish the consolidation of three sections of the Revised Code into one, and to comply with federal regulations.

Health benefit plan

The act does not alter the types of benefit plans that were subject to external review under former law. Under the act, "health benefit plan" means a policy, contract, certificate, or agreement offered by a health plan issuer to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services. Under the act, as under former law, the following types of policies are excluded: specific accident, accident only, credit, dental, disability income, long-term care, hospital indemnity, Medicare supplement, Medicare, tricare, specified disease, or vision care; coverage issued as a supplement to liability insurance; insurance arising out of workers' compensation or similar law; automobile medical payment insurance; or insurance under which benefits are payable with or without regard to fault and which is statutorily required to be contained in any liability insurance policy or equivalent self-insurance. The act also expressly excludes a Medicare supplement policy of insurance, as defined by the Superintendent, coverage under a plan through Medicare, Medicaid, or the federal employees benefit program; any coverage issued under the United States Armed Services Medical and Dental Care Law (Chapter 55 of Title 10 of the United States Code) and any coverage issued as a supplement to that coverage.⁸

Health plan issuer

To consolidate all external review processes under one chapter, the act defines "health plan issuer" as an entity subject to the Insurance Laws and rules of Ohio, or subject to the Superintendent's jurisdiction, that contracts to provide, deliver, arrange for, pay for, or reimburse any of the costs of health care services, including a sickness and accident insurance company, a health insuring corporation, a fraternal benefit society, a self-funded multiple employer welfare arrangement, or a nonfederal, government health plan. "Health plan issuer" includes a third party administrator to

⁷ R.C. 1751.85, 3923.68, and 3923.77 (repealed by the act).

⁸ R.C. 3922.01(L) and R.C. 3923.66(B) and 3923.75(B) (repealed by the act).

the extent of the services that such an entity is contracted to provide under a health benefit plan.⁹

Adverse benefit determination

The act expands the definition of adverse benefit determination, as compared to former law. An adverse benefit determination is defined as a decision by a health plan issuer to deny, reduce, or terminate a requested health care service or payment, in whole or in part, including all of the following:

- A determination that the service does not meet the health plan issuer's requirements for medical necessity, appropriateness, setting, level of care, or effectiveness, including experimental or investigational treatments;
- A determination that a person is ineligible for coverage under the associated plan or policy;
- A determination that a requested service is not a covered benefit;
- The imposition of an exclusion.

"Adverse benefit determination" also includes a decision not to issue coverage to an individual or group and a decision to rescind coverage on a health benefit plan.¹⁰

Authorization for external appeal

The act expressly authorizes covered individuals to make a request for an external review and specifies that such a request for standard reviews must be made in writing and within 180 days of receipt of notification of an adverse benefit determination. For an expedited review, a request may be made either by oral or electronic means, but written confirmation of such a request must be provided to the health plan issuer within five days.¹¹ This is unchanged as compared to former law.¹²

Removal of \$500 limit

The act removes the \$500 threshold for claims to qualify for the external (and internal review process). Under former law, for an adverse benefit determination (or

⁹ R.C. 3922.01(P).

¹⁰ R.C. 3922.01(A).

¹¹ R.C. 3922.02.

¹² R.C. 1751.84(C)(1), 3923.67(C)(2), and 3923.76(C)(2) (repealed by the act).

denial or reduction of a benefit claim) to be eligible for external review, the claim must have been for an amount greater than \$500.¹³ However, in those situations where a request for an expedited claim was made or covered person had a terminal condition, there was no such threshold.¹⁴ Under the act, there is no minimum claim amount threshold, and all claims are eligible for external review regardless of the size of the claim.¹⁵

Internal appeals

The act requires all health plan issuers to implement an internal appeals process in compliance with the Federal Patient Protection and Affordable Care Act of 2010, and to notify covered persons of this internal appeals process, the external review process, and any related assistance that might be available from the Superintendent.¹⁶

Continuing law requires health insuring corporations to maintain an internal appeal process but prior law appeared only to contemplate internal review processes by sickness and accident insurers and public employee health benefit plans.¹⁷

Exhaustion of internal appeal

The act requires a covered person to exhaust a health plan issuer's internal appeal process before the covered person's adverse benefit determination is eligible for external review.¹⁸ This was also the case under prior law.¹⁹

Under the act, the internal appeal process is considered exhausted if the covered person has not received a decision on the appeal from the health plan issuer in 30 days time or the health plan issuer fails to adhere to all requirements of the internal appeals process. However, the act also authorizes health plan issuers to violate this 30-day exhaustion deadline if it can demonstrate that all of the following are met:

- The violation is de minimis and does not cause prejudice or harm to the covered person;

¹³ R.C. 1751.84(A)(2), 3923.67(A)(2), and 3923.76(A)(2) (repealed by the act).

¹⁴ R.C. 1751.84(A)(2), 1751.85, 3923.67(A)(2), 3923.68, 3923.76(A)(2), and 3923.77 (repealed by the act).

¹⁵ R.C. 3922.02(C).

¹⁶ R.C. 3922.03(A) and (C).

¹⁷ R.C. 1751.83 and R.C. 3923.67 and 3923.76 (repealed by the act).

¹⁸ R.C. 3922.04(A).

¹⁹ R.C. 1751.84(B)(2), 3923.67(B)(2), and 3923.76(B)(2) (repealed by the act).

- The violation was for good cause or due to matters beyond the health care issuer's control;
- The violation occurred in the context of an ongoing, good faith exchange of information;
- The violation is not reflective of a pattern or practice of noncompliance.²⁰

If a health plan issuer violates the 30-day exhaustion deadline, a covered person requests an external review, and the health plan issuer denies the request because the violation meets the criteria listed above, the health plan issuer must provide an explanation of the denial within ten days upon request. In such a situation, the covered person may request that the Superintendent review the health plan issuer's explanation. If the Superintendent upholds the health plan issuer's explanation, the covered person has ten days to re-enter the internal appeal process.²¹

Also, under the act, the health plan issuer may waive the 30-day exhaustion deadline.²²

Prohibition related to utilization reviews

Under the act, a covered person is prohibited from requesting an external review of an adverse benefit determination until the internal appeal process is complete if the adverse benefit determination involved a retrospective review determination and was made pursuant to a utilization review, regardless of how long it takes to complete the internal appeals process.²³

Levels of review

The act prohibits health plan issuers offering individual coverage from requiring more than one level of internal appeal before a covered person may request an external review.²⁴

²⁰ R.C. 3922.04(B) and (C).

²¹ R.C. 3922.04(C).

²² R.C. 3922.04(E).

²³ R.C. 3922.04(D).

²⁴ R.C. 3922.04(F).

Review process – general provisions

The act prescribes, with greater detail than former law, the process for external reviews. If a request for an external review is complete, the health plan issuer is required to initiate the external review and to provide notification to the covered person that includes both of the following:

- The name and contact information for the assigned independent review organization, or the Superintendent, as applicable;
- A statement that the covered person may submit additional information to either the external review or Superintendent, as applicable, within ten days.

If a request for an external review is incomplete, the health plan issuer must provide notification of such to the covered person and inform the covered person of the needed information.²⁵

Denial and notifications

If a health plan issuer denies a request for an external review because the adverse benefit determination in question is ineligible, the health plan issuer must provide a notification to the covered person that includes both of the following:

- The reason for the denial;
- That the denial may be appealed to the Superintendent.

The act stipulates that if a health plan issuer denies a request for an external review due to the ineligibility of the associated adverse benefit determination, a covered person may appeal this denial to the Superintendent and that the Superintendent may allow an external review.²⁶

Assignment of independent review organization

Under the act, the Superintendent is required to assign an independent review organization on a random basis from those qualified to conduct the review based on the nature of the health care service in question. The Superintendent is prohibited from

²⁵ R.C. 3922.05(A) to (D).

²⁶ R.C. 3922.05(E).

choosing an external review organization with a conflict of interest.²⁷ This prohibition existed in former law as well.²⁸

External review organizations unbound

The act specifically states that independent review organizations are not bound by any decisions reached by the health plan issuer during its utilization review process or internal appeals process. The organization may, but is not required to, accept and consider additional information submitted by the covered person after the ten-day submission deadline.²⁹

Review deadlines

The act decreases the amount of time that independent review organizations have to make a decision in expedited review cases from seven days to 72 hours. This deadline is the same regardless of whether or not a covered person has a terminal illness. The deadline for decisions in the case of non-expedited reviews remains unchanged, as compared to prior law, at 30 days.³⁰

Notification of determination

When a determination is made under the act, the independent review organization must provide written notification of the determination to the covered person, the health plan issuer, and the Superintendent. The notification must include all of the following:

- A general description of the reason for the request for external review;
- The date the review organization was assigned by the Superintendent;
- The dates over which the external review was conducted;
- The date on which the decision was reached;
- The rationale for the organization's decision;

²⁷ R.C. 3922.05(F).

²⁸ R.C. 3901.80(C) (repealed by the act).

²⁹ R.C. 3922.05(G).

³⁰ R.C. 3922.05(H)(1) and R.C. 1751.84(D)(9)(a), 1751.85(C)(7)(a), 3923.67(D)(9)(a), 3923.68(C)(7)(a), 3923.76(D)(9)(a), and 3923.77(C)(7)(a) (repealed by the act).

- References to the evidence that was considered in reaching its decision.³¹

If a health plan issuer receives a notice by an independent review organization to reverse the adverse benefit determination, the health plan issuer must immediately provide coverage for the health care service or services in question.³²

Reconsideration of adverse benefit determination

The act requires independent review organizations, except in the case of an expedited review, to forward any information received from the covered person related to the adverse benefit determination to the health plan issuer. Upon receipt of such information, a health plan issuer may reconsider the adverse benefit determination. The act stipulates that such a reconsideration must not delay or terminate any associated external review. If, after reconsideration, a health plan issuer decides to provide coverage for a requested service, the issuer is required to notify, in writing and within one business day, the covered person, the independent review organization of its decision. Upon receipt of such a notification, an independent review organization must terminate its review.³³

Information that must be considered

In addition to any information provided by the covered person or the health plan issuer pursuant to the initiation of an external review, the independent review organization must consider all of the following when conducting its review:

- The covered person's medical records;
- The attending health care professional's recommendation;
- Consulting reports from health care professionals;
- The terms of the covered person's health benefit plan;
- The most appropriate practice guidelines;
- Any applicable clinical review criteria developed by the health plan issuer;

³¹ R.C. 3922.05(H)(2).

³² R.C. 3922.05(I), 3922.09(H), and 3922.10(N).

³³ R.C. 3922.06 and 3922.10(L).

- The opinion of the review organization's clinical reviewer or reviewers.³⁴

Standard reviews – specific provisions

Upon initiating an external review, a health plan issuer is required to provide all information used in making the adverse benefit determination in question of receiving a complete and valid request for an external review. The act prohibits an external review from being delayed due to lack of receipt of such information and, unlike former law, authorizes an independent review organization to overturn an adverse benefit determination if such information is not received. In such a situation, if an adverse benefit determination is overturned, the independent review organization must provide notice to the covered person, the health plan issuer, and the Superintendent within one business day.³⁵

Expedited review – specific provisions

Initial adverse benefit determinations

Under the act, a covered person is eligible for an expedited external review after an initial adverse benefit determination if both of the following conditions are met:

- The covered person's treating physician certifies that the associated medical condition could seriously jeopardize the life or health of the covered person if treated after the time frame of an expedited internal review;
- The covered person has filed a request for an expedited internal review.³⁶

Final adverse benefit determinations

Under the act, a covered person is eligible for an expedited external review after a final adverse benefit determination (an adverse benefit determination that is upheld at the completion of an internal appeals process) if either of the following conditions are met:

- The covered person's treating physician certifies that the associated medical condition could seriously jeopardize the life or health of the covered person, or would jeopardize the covered person's ability to regain

³⁴ R.C. 3922.07.

³⁵ R.C. 3922.08 and R.C. 1751.84(D)(6), 3923.67(D)(6), and 3923.76(D)(6) (repealed by the act).

³⁶ R.C. 3922.09(A)(1).

maximum function, if treated after the time frame of a standard internal review;

- The final adverse benefit determination concerns an emergency service that the covered person has received, but has not yet been discharged from the associated facility.³⁷

Expedited external reviews are not provided for retrospective final adverse benefit determinations.³⁸

Overturing an adverse benefit determination due to lack of information

Similar to a standard review, a health plan issuer is required to forward all information in the making of any adverse benefit determination, and an independent review organization may overturn an adverse benefit determination if such information is not received. The independent review organization must uphold or reverse the adverse benefit determination within 72 hours after being assigned. The independent review organization must promptly notify the covered person, the health plan issuer, and the Superintendent of its decision and provide written confirmation of the decision within 48 hours.³⁹

Experimental and investigational treatment reviews – specific provisions

The act prescribes a separate process for reviewing those situations in which an experimental or investigational treatment has been requested, except when a requested health service is specifically excluded under a covered person's policy. A covered person may also request an expedited experimental review under the act. Similar to standard and expedited reviews, an independent review organization may overturn an adverse benefit determination if required information related to the initial determination is not provided within five days, for a standard experimental review, or immediately, in the case of an expedited experimental review.⁴⁰

Experimental review eligibility

To be eligible for an experimental external review, a covered person's treating physician must certify that one of the following is applicable:

³⁷ R.C. 3922.01(K) and 3922.09(A)(2).

³⁸ R.C. 3922.09(I).

³⁹ R.C. 3922.09(B) to (G).

⁴⁰ R.C. 3922.10.

- Standard health services have not been effective in improving the condition of the covered person;
- Standard health services are not medically appropriate for the covered person;
- There is no standard health service that is more effective than the requested service.⁴¹

Clinical reviewers

Under the act, in conducting an experimental review, an independent review organization must select at least one clinical reviewer. The clinical reviewer is required to be a physician or other appropriate health care professional who has at least three years of experience in the relevant area and have a knowledge of the requested service.⁴² The act prohibits both the covered person and the health plan issuer from having any control over the choice of the clinical reviewer.⁴³ A chosen clinical reviewer is required to issue a written opinion on whether the adverse benefit determination should be upheld or reversed that includes all of the following:

- A description of the covered person's condition;
- A description of the indicators relevant to determining whether the requested therapy is more likely to be more beneficial than any available health care service;
- A description and analysis of any evidence considered in reaching the opinion;
- A description and analysis of any evidence-based standards considered;
- Whether the opinion was based on the fact that federal Food and Drug Administration has approved the treatment for the associated condition, or if evidence indicates that the requested therapy indicates that the requested health service is likely to be more beneficial than standard therapies.⁴⁴

⁴¹ R.C. 3922.10(B).

⁴² R.C. 3922.10(E) and (F).

⁴³ R.C. 3922.10(G).

⁴⁴ R.C. 3922.10(H) and (K).

An independent review organization may choose more than one clinical reviewer.⁴⁵ If more than one clinical reviewer is chosen, and the reviewers are evenly split on whether or not to overturn the adverse benefit determination, the organization is required to get the opinion of an additional clinical reviewer.⁴⁶

In addition to the general information required to be considered, as well as any information related to the adverse benefit determination provided by the health plan issuer, the clinical reviewer must consider whether or not the federal Food and Drug Administration has approved the treatment for the associated condition, whether or not evidence indicates that the requested therapy indicates that the requested health service is likely to be more beneficial than standard therapies.⁴⁷

The act requires that the independent review organization's determination be based upon the opinion of the clinical reviewer or a majority of reviewers, as applicable. An independent review organization is required to provide notification of its decision to the covered person, the health plan issuer, and the Superintendent (30 days generally, 72 hours in the case of an expedited review). All of the following information is required to be included in this notice:

- A general description of the reason for the request for external review;
- The written opinion of each clinical reviewer;
- The date the review organization was assigned by the Superintendent;
- The dates over which the external review was conducted;
- The date on which the decision was reached;
- The rationale for the organization's decision.⁴⁸

Experimental reviews under former law

Former law allowed for experimental treatment reviews to be conducted only in those cases where the covered person had a terminal illness that could not be treated with standard therapies. Under former law, with certain exceptions, experimental reviews were conducted by a panel of at least three physicians or other relevant

⁴⁵ R.C. 3922.10(E)(1).

⁴⁶ R.C. 3922.10(M)(2)(c).

⁴⁷ R.C. 3922.10(K).

⁴⁸ R.C. 3922.10(E)(2) and (M).

providers.⁴⁹ The process for conducting an experimental review was largely similar to the process prescribed under the act in all other particulars.

Contractual reviews and emergency reviews

The act requires the Superintendent to establish and maintain a process for reviewing adverse benefit determinations that involve a contractual issue and not a medical issue, which is consistent with continuing law. An adverse benefit determination is not eligible for external review by the Superintendent unless the covered person has exhausted the internal appeal process of the health plan issuer. If the Superintendent determines that the adverse benefit determination involves a medical issue, then the Superintendent is required to initiate an external review via an independent review organization. Otherwise, the Superintendent is required to make a determination and provide notice of the determination to the covered person and health plan issuer.

For an adverse determination in which emergency medical services have been determined to be not medically necessary or appropriate after an external review, the health plan issuer must afford the covered person the opportunity for an external review by the Superintendent, based on the prudent layperson standard.⁵⁰

Decisions of independent review organizations are binding

The act stipulates that the decision of an independent review organization is binding on both the health plan issuer and the covered person, except to the extent that either has other remedies under applicable law, or unless the Superintendent determines that a second external review is required. If an independent review organization overturns an adverse benefit determination, a health plan issuer is required to provide coverage for the requested health service. Also, a covered person may not file a subsequent request for external review involving the same adverse benefit determination, except in the event that new medical or scientific evidence is submitted to the health plan issuer.⁵¹

Independent review organization accreditation

The act requires the Superintendent to accredit independent review organizations, to prescribe a form for doing so, and to maintain a list of accredited independent review organizations for the purposes of assigning them to conduct

⁴⁹ R.C. 1751.85, 3923.68, and 3923.77 (repealed by the act).

⁵⁰ R.C. 3922.11 and R.C. 1751.831, 3923.66(C), and 3923.75(C) (repealed by the act).

⁵¹ R.C. 3922.12.

external reviews. Under the act, in order to receive accreditation by the Superintendent, an independent review organization must also be accredited by a nationally recognized private accrediting entity with standards equivalent or greater to minimum standards established by the Superintendent. But, if no acceptable nationally recognized private accrediting entity exists to provide accreditation, the Superintendent may approve the independent review organization. The act makes provision for reviewing the standards of national accreditation organizations on a periodic basis.⁵² Prior law only authorized the Superintendent to take into consideration the standards established by national accrediting organizations.⁵³

Independent review organizations must renew their accreditations on an annual basis. If the Superintendent determines, at any time, that the review organization has lost its national accreditation or no longer satisfies the minimum requirements for accreditation, the Superintendent is required to revoke the organization's accreditation.⁵⁴

Minimum qualifications

In order to meet the minimum qualification requirements set out by the Superintendent, an independent review organization must develop and maintain written policies governing its external review policies that do all of the following:

- Ensure that external reviews are conducted within the required timeframes and that all required notifications are provided;
- Ensure the selection of qualified and impartial clinical reviewers;
- Ensure that clinical reviewers are suitably matched to external reviews and that the independent review organization engages sufficient clinical reviewers to meet this requirement;
- Ensure the confidentiality of medical records and clinical review criteria;
- Ensure that any person employed by, or under contract with, the independent review organization adheres to the requirements of the law pertaining to external review.

⁵² R.C. 3922.13 and 3922.14(D).

⁵³ R.C. 3901.80 (repealed by the act).

⁵⁴ R.C. 3922.13.

The independent review organization must also maintain a toll-free telephone service and agree to maintain data on the external reviews it conducts in order to meet reporting requirements. An independent review organization must be unbiased and maintain policies to ensure this.⁵⁵

Conflict of interest

The act stipulates that independent review organizations may not own or control, be owned or in any way controlled by, or exercise control with a benefit plan, a national, state, or local trade association of benefit plans, or a national, state, or local trade association of health care providers. The act also prohibits conflicts of interest, prescribing such conflicts as a relationship between the independent review organization and the covered person, the health plan issuer, the provider, the facility, or the manufacturer of the requested drug or service. The act authorizes the Superintendent to act on conflicts of interest that do not strictly meet the criteria listed above, but that are apparent. In any situation where a conflict of interest exists, the Superintendent is required to disallow the independent review organization from conducting the external review in question.⁵⁶

Former law similarly prohibited conflicts of interest, but with less specificity.⁵⁷

Qualification of clinical reviewers

In order to be qualified to conduct external reviews, a clinical reviewer must meet all of the following qualifications:

- Have the same license as the health care provider of the service in question;
- Be an expert on the medical condition in question with related, clinical experience within the last three years;
- Hold a non-restricted license;
- Have no history of disciplinary action.⁵⁸

⁵⁵ R.C. 3922.14(A) and (E).

⁵⁶ R.C. 3922.14(B) to (C).

⁵⁷ R.C. 1751.84(D), 1751.85(C), 3923.67(D), 3923.68(C), 3923.76(D), and 3923.77(C) (repealed by the act).

⁵⁸ R.C. 3922.15 and R.C. 1751.85(C)(2), 3901.81, 3923.68(C)(2), and 3923.77(C)(2) (repealed by the act).

Reporting requirements

Independent review organizations

An independent review organization is required under the act to maintain for at least three years information related to the external reviews it conducts and to report that information upon request of the Superintendent. The report is required to include all of the following, grouped by state and by each health plan issuer:

- The total number of requests for external review;
- The number of external reviews completed, broken down by adverse benefit determinations upheld and reversed;
- The average length of time needed to complete an external review;
- The types of health care services requested or cases for which an external review was sought;
- The number of external reviews that were terminated as the result of a reconsideration by the health plan issuer after the receipt of additional information from the covered person;
- The costs associated with external reviews;
- The medical specialty of clinical reviewers used to conduct each external review.⁵⁹

Health plan issuers

Similarly, health plan issuers are required to maintain records for at least three years on all requests made for an external review and are required to provide this information in accordance with any rules, policies, or procedures adopted by the Superintendent.⁶⁰

Report by the Superintendent

Similar to prior law, the Superintendent is required to produce an annual report of the information collected related to external reviews. The report is to be provided to the Governor, the Speaker and Minority Leader of the House of Representatives, the President and Minority Leader of the Senate, and the chairs and ranking minority

⁵⁹ R.C. 3922.17(A) and R.C. 3901.82 (repealed by the act).

⁶⁰ R.C. 3922.17(B).

members of the House and Senate committees with jurisdiction over health and insurance issues.⁶¹

Notification requirements

The act substantially increases the number and type of notifications that must be provided to covered persons throughout the external review process.⁶²

Notifications under the act

Under the act, a health insurer must include a description of its external review procedures along with any evidence of coverage it provides. This notice must include: a statement explaining that an external review is available when an adverse benefit determination is made; the contact information of the Superintendent, and notice that if a covered person requests an external review, then he or she must release medical records as necessary to conduct the review.

When a health plan issuer provides notice of an adverse determination, the issuer must also provide written notice of the covered person's right to an external review. This notice has to include all of the following:

- Claim identification information;
- A description of the reason for the adverse benefit determination;
- A description of the standard that was used to make the determination;
- A description of the available internal appeals and external review process;
- Information on the availability of assistance from the Superintendent and contact information for the Superintendent.⁶³

Non-final adverse benefit determinations

When an adverse benefit determination notification is made in situations in which the determination has not been upheld at the completion of an internal appeal process, certain additional procedures must be followed. The health plan issuer must notify the covered person that, if the covered person's treating physician certifies that

⁶¹ R.C. 3922.17(C) and R.C. 3901.82(D) (repealed by the act).

⁶² R.C. 3922.19.

⁶³ R.C. 3922.19(A) to (C).

the covered person's life or health or ability to regain maximum function could be jeopardized if the requested treatment is postponed until after an expedited internal appeal is made, then the covered person may request that an expedited external review be conducted simultaneously with the expedited internal appeal. Similarly, if the adverse benefit determination involves a denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational and the covered person's treating physician certifies in writing that the service or treatment would be significantly less effective if not promptly initiated, the covered person may file a request for an expedited external review to be conducted simultaneously with the expedited internal appeal. The health plan issuer must also notify the covered person that if an internal appeal is requested, and if no decision is made on the appeal within 30 days, then the internal appeal process is considered exhausted and the person may request an external review.⁶⁴

Final adverse benefit determinations

Certain notifications must be made to covered individuals along with notification of an adverse benefit determination at the end of the internal appeal process, including notification that:

- A written request for an external review must be submitted within 180 days;
- A covered person may request an expedited external review if the covered person's physician certifies that postponement of a requested service could seriously jeopardize the covered person's life or health or ability to recover maximum function;
- If the adverse benefit determination involves emergency services, which have been received, but the covered person has not yet been released, the covered person may request an expedited external review.⁶⁵

If the final adverse benefit determination concerns denial of coverage based on a determination that the recommended or requested health care service or treatment is experimental or investigational, and if the covered person's treating physician certifies in writing that the service or treatment would be significantly less effective if not promptly initiated, the covered person may request an expedited external review.

⁶⁴ R.C. 1751.83 and 3922.19(D).

⁶⁵ R.C. 3922.19(E).

Additional information to be provided

The bill requires a health plan issuer to include a description of both the standard and expedited external review procedures alongside any notice of an adverse benefit determination, final or non-final. The description must highlight relevant sections of the Revised Code that give the covered person the opportunity to submit additional information. A health plan issuer must also include any forms used to process an external review, including a form that authorizes the health plan issuer and the health care provider to disclose protected health information related in any way to the external review.⁶⁶

Notifications under prior law

Non-terminal illness

Under former law, after an internal review a health insuring corporation had to provide a written response to each request for an internal review not later than 60 days after the request was made. The requirement for a written response still exists under continuing law, but the act changed the time frame for such a response to 30 days. The response still must include the following:

- The reason for the health insuring corporation's decision;
- Notification of the enrollee's right to pursue a further review;
- An explanation of the procedures for initiating the review, including the time frames within which the enrollee must request the review.⁶⁷

If an independent review organization did not reach a conclusion because it had not received all information necessary to do so, it was required to notify the covered person and the health plan issuer.⁶⁸ Also, for all health plan issuers, if at any time during the external review process the health plan issuer decided to provide coverage for a requested health service, the health plan issuer had to provide notice of this decision to the covered person.⁶⁹

⁶⁶ R.C. 3922.19(F).

⁶⁷ R.C. 1751.83.

⁶⁸ R.C. 1751.84(D)(6)(b), 3923.67(D)(6)(b), and 3923.76(D)(6)(b) (repealed by the act).

⁶⁹ R.C. 1751.84(D)(7), 3923.67(D)(7), and 3923.76(D)(7) (repealed by the act).

Terminal illness

Under former law, covered individuals with a terminal illness who were covered by a sickness and accident policy or by a public employee benefit plan must have been notified of his or her right to an external review within 30 business days of an adverse benefit determination.⁷⁰ Also, for all health plan issuers, if at any time during the external review process the health plan issuer decided to provide coverage for a requested health service, the health plan issuer had to provide notice of this decision to the covered person.⁷¹

Rules

The act authorizes the Superintendent to adopt rules to administer the law related to external review and requires the Superintendent to prescribe forms related to notices, appeals, and requests for review.⁷²

Current law maintained under consolidated section

Under the new consolidated external review chapter, the act maintains current law related to the following topics:

- No cause of action against independent review organizations, employers, and health plan issuers;⁷³
- Admissibility as evidence of reports by independent review organizations;⁷⁴
- The liability of independent review organizations;⁷⁵
- The cost of external reviews being borne by health plan issuers;⁷⁶

⁷⁰ R.C. 3923.68(C)(1) and 3923.77(C)(1) (repealed by the act).

⁷¹ R.C. 1751.85(D), 3923.68(E), and 3923.77(E) (repealed by the act).

⁷² R.C. 3922.22.

⁷³ R.C. 3922.16 and R.C. 1751.87, 3923.69, and 3923.78 (repealed by the act).

⁷⁴ R.C. 3922.20 and R.C. 1751.88, 3923.70, and 3923.79 (repealed by the act).

⁷⁵ R.C. 3922.16(B) and (C) and R.C. 1751.87, 3901.84, 3923.69, and 3923.78 (repealed by the act).

⁷⁶ R.C. 3922.18 and R.C. 1751.84(D)(4) and (5), 1751.85(C)(5), 3923.67(D)(4) and (5), 3923.68(C)(5), 3923.76(D)(4) and (5), and 3923.77(C)(5) (repealed by the act).

- Confidentiality of records;⁷⁷
- Violations of the law related to external reviews.⁷⁸

Conforming changes

The act makes a number of conforming changes throughout the Revised Code.⁷⁹

Effective date

The act stipulates that the new laws related to external reviews apply to those external reviews requested or initiated on or after January 1, 2012.⁸⁰

Medical reference compendia

The act revises the list of standard medical reference compendia that health insurers (health insuring corporations and sickness and accident insurers) that provide prescription drug coverage may use when determining whether a drug is safe and effective for treatment of a particular indication. The act replaces the prior statutory list with a reference to the standard compendia adopted by the U.S. Department of Health and Human Services. The following table shows the differences between the two lists of acceptable medical reference compendia:

Prior law	The act
American Medical Association Drug Evaluations	American Medical Association Drug Evaluations
American Hospital Formulary Service – Drug Information	American Hospital Formulary Service – Drug Information
Drug Information for the Health Care Provider (United States Pharmacopoeia Convention)	—
—	United States Pharmacopoeia – Drug Information
—	Any other authoritative compendia identified by the U.S. Secretary of Health and Human Services

⁷⁷ R.C. 3922.21 and R.C. 1751.19 (not in the act).

⁷⁸ R.C. 3922.23 and 1751.35, R.C. 3923.681 (repealed by the act), and 1751.45 (not in the act).

⁷⁹ R.C. 1751.11, 1751.33, 1751.35, 1751.77, 1751.78, 1751.811, 1751.87, 1751.89, 3901.045, and 4731.36.

⁸⁰ Section 3 of the act.

Continuing law prohibits health insuring corporation and sickness and accident insurance policies, contracts, and agreements that provide coverage for prescription drugs from limiting or excluding coverage for any drug approved by the United States Food and Drug Administration on the basis that the drug has not been approved by the United States Food and Drug Administration for the treatment of the particular indication for which the drug has been prescribed if the drug has been recognized as safe and effective for treatment of the indication in one or more specified standard medical reference compendia (revised by the act) or in medical literature that satisfies specified criteria.⁸¹

HISTORY

ACTION	DATE
Introduced	05-04-11
Reported, H. Insurance	06-15-11
Passed House (97-0)	06-22-11
Reported, S. Insurance, Commerce and Labor	09-20-11
Passed Senate (31-0)	09-20-11
House concurred in Senate amendments (96-0)	09-21-11

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⁸¹ R.C. 1751.66(A) and (B) and 3923.60(A) and (B) and, by reference, 42 U.S.C. 1395x(t)(2).

