Employee Benefits Explanations/New Developments, ¶10,425, Health Plan Claim Procedures, Adverse Benefit Determinations, and Appeals

Employee Benefits Explanations/New Developments
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ERISA regulations impose minimum requirements for employee benefit plan procedures pertaining to claims for benefits by participants and beneficiaries. Every employee benefit plan must establish and maintain reasonable procedures governing the filing of benefit claims, notification of benefit determinations, and appeal of adverse benefits determinations (i.e., claims procedures) ([.01]).

Health reform implementation. In July 2010, the IRS, EBSA, and the HHS issued interim final regulations that added new requirements for internal claims procedures and appeals ([.05]). The rules implement the claims procedures requirements in Public Health Service Act Sec. 2719, as added by the Patient Protection and Affordable Care Act (ACA) (P.L. 111-148). On June 24, 2011, the IRS, EBSA, and the HHS amended the rules issued in July 2010 ([.07]). The amendments to the interim final regulations are effective as of July 22, 2011. Final regulations were issued in November 2015. The final rules apply to plan years beginning on or after January 1, 2017 ([.09]). The ACA-related interim final and final regulations are discussed below (see “Appeals process under the Patient Protection and Affordable Care Act”).

General rules

Plans subject to the rules. All employee benefit plans as defined under ERISA Sec. 4(a), including ERISA group health and disability plans, are subject to the rules on claims procedures. "Group health plan" is defined as "an employer welfare benefit plan within the meaning of section 3(1) [ERISA Sec. 3(1)] of the Act to the extent that such plan provides "medical care" within the meaning of section 733 of the Act [ERISA Sec. 733]" ([.10]). Thus, plans that cover expenses relating to the diagnosis, cure, mitigation, treatment, or prevention of disease, including transportation and insurance expenses, are subject to the rules. Disability plans are not defined under the regulations.

Long-term care plans are specifically not subject to the regulations and benefit plans excepted in ERISA Sec. 733 are also not subject to the rules ([.12]). Also, plans mentioned in ERISA Sec. 4(b), such as church plans and governmental plans, are specifically exempt.

Summary plan descriptions must be updated. The SPDs of group health plans must describe all claims procedures, including any procedures for obtaining prior approval as a prerequisite for obtaining a benefit, such as preauthorization procedures or utilization review procedures. SPDs must also discuss all applicable time frames ([.14]).

Conflicts of interest. The rules contain standards regarding avoiding conflicts of interest. In the case of a plan providing disability benefits, the plan must ensure that claims and appeals are adjudicated in a manner designed to ensure independence and impartiality of the persons involved in making the decision. As such, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical or vocational expert) must not be made based upon the likelihood that the individual will support the denial of benefits ([.15]).

Right to appoint representative. The claims procedure of an ERISA-covered plan cannot “preclude an authorized representative of a claimant from acting on behalf of such claimant in pursuing a benefit claim or appeal of an adverse benefit determination.” In addition, prior department guidance on the claims procedure regulation confirms that authorized representatives are entitled to notifications in connection with initial claim determinations and appeals. Although a plan may establish reasonable procedures for determining whether an individual has been authorized to act on behalf of a claimant, the procedure cannot prevent claimants from choosing for themselves who will act as their representative or preclude them from designating an authorized

representative for the initial claim, an appeal of an adverse benefit determination, or both. The plan must include any procedures for designating authorized representatives in the plan's claims procedures and in the plan's summary plan description (SPD) or a separate document that accompanies the SPD. SPDs must satisfy the style and format requirements for SPDs in ERISA Reg. §2520.102-2, and include a statement that the plan's claims procedures are furnished automatically, without charge, as a separate document ([.16]).

Time frames for responding to health claims

The time frames for responding to health claims depends on whether the claim is:

- "urgent" (generally, no later than 72 hours after receipt of claim by the plan);
- "pre-service" (generally, no later than 15 days after receipt of claim); or
- "post-service" (generally, no later than 30 days after receipt of claim).

"Urgent" claims. In general, plan administrators must respond to urgent care claims as soon as possible, but in no event later than 72 hours within receipt of the claim ([.17]). Urgent claims are defined as claims for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations:

1. seriously jeopardizes the life or health of the claimant or the ability of the claimant to regain maximum function; or
2. would, in the opinion of a physician with knowledge of the claimant's condition, subject the claimant to severe pain that cannot be adequately managed without the proposed immediate care ([.18]).

Whether a claimant presents an "urgent" claim under the first test may be determined by any person acting on behalf of the plan applying the judgment of a "prudent layperson who possesses an average knowledge of health and medicine" ([.20]). Therefore, the plan need not necessarily appoint a person with medical expertise to make such determinations.

If a physician familiar with the claimant's medical condition intervenes and informs the plan administrator that the claim is "urgent" under either test, the claim must thus be treated as "urgent"([.21]).

There are two exceptions to the 72-hour time frame rule for urgent claims. In the event an urgent claim is incomplete, or lacks information necessary to make a determination, the plan administrator must notify the claimant as soon as possible (but not later than 24 hours after receipt of the claim) of the specific information needed to complete the claim ([.22]). The claimant then must be afforded a minimum of 48 hours to submit a "clean claim," although plans are free to extend that time period. The plan administrator would then be required to make a determination on the claim no later than 48 hours after the earlier of:

- the plan's receipt of the specified information, or
- the end of the period afforded the claimant to provide additional information ([.23]).

No other extensions are allowed under the urgent claim process.

Shorter time frame for ongoing treatment claims of urgent nature. The second exception involves ongoing courses of treatment provided over a period of time that are urgent in nature. In the event a participant or beneficiary requests to continue treatments beyond the period initially approved by the plan, plans have only 24 hours within receipt of that request to act upon the claim. However, quick action is only required if the participant or beneficiary has requested continued treatment within 24 hours prior to the expiration of the initially prescribed period ([.24]). The rationale behind this shortened time frame is that quick action may be needed to minimize the possibility of harm from interruptions in treatment ([.25]).

With respect to urgent claims for ongoing treatment, how should the claim be treated if the participant has failed to present his/her claim within the 24 hour time frame? The regulations are unclear; however, given the DOL's expressed desire to expedite the claims process, the more prudent course of action would be to decide the claim

as a regular "urgent care claim"— "as soon as possible," but no later than 72 hours.

"Pre-service" claims. In general, plan administrators must respond to pre-service claims within a "reasonable time period," but in no event later than 15 days after receipt of a claim ([.27]). A pre-service claim is defined as a claim for health benefits with respect to which the terms of the plan condition receipt of the benefit, in whole or in part, on prior approval of the plan ([.28]).

Again, there are two exceptions to this requirement ([.29]). First, if a plan administrator determines that it cannot act upon the claim due to "matters beyond the control of the plan," the plan may extend the time frame by an additional 15 days. This relief is available only once and requires the plan to notify the claimant of the extension some time prior to the expiration of the initial 15-day time period. The regulations are silent as to what will be considered acceptable circumstances to warrant a 15-day extension.

Second, if the claimant has failed to submit a "clean claim" (which is a claim that contains all the necessary information for making a determination), the plan must so notify the claimant within the initial 15-day time period. The claimant must then be afforded at least 45 additional days to submit a clean claim, although plans are free to extend the 45 day time frame.

Special notice rule pertaining to pre-service and urgent claims. For pre-service and urgent care claims, plan administrators must provide notice in the event that plan procedures for filing claims are not followed ([.295]). The notice must be:

- provided to the claimant or authorized representative; and
- delivered to the claimant " as soon as possible," but no later than five days (or 24 hours for urgent care claims) following the failure.

Notice may be oral, unless written notice is requested by the claimant. The notice requirement is triggered "only by a communication from a claimant or a health care professional representing the claimant that specifies the identity of the claimant, a specific medical condition or symptom, and a specific treatment, service, or product for which approval is requested." In addition, the communication must be received by a person responsible for handling benefit matters.

"Post-service" claims. In general, a plan administrator must act upon a post-service claim within a "reasonable time period," but in no event later than 30 days after receipt ([.30]). A post-service claim is defined as a claim for a benefit "that is not a pre-service claim" ([.31]), and would include, for example, claims for payment or reimbursement.

The two exceptions to the 30-day requirement are identical to the exceptions discussed above with respect to pre-service claims, namely, that a plan administrator may have an additional 15 days if it needs the additional time due to circumstances beyond its control, or if the claimant has failed to submit a clean claim.

Disability claims. In general, a plan administrator must respond to a claim for disability benefits no later than 45 days of receipt of the claim. A 30-day extension is available if necessary due to matters beyond the control of the plan. Unlike pre-service and post-service claims, this time period may be extended a second time for 30 days if the plan is still unable to make a determination due to circumstances beyond its control ([.32]).

Calculating time periods. The time period within which benefit determinations must be made commences at the time a claim is filed in accordance with plan procedures, even if some information is missing from the claim. To the extent that the plan requests an extension of time to obtain more complete information from the claimant, the period for making the benefit determination begins on the date the plan notifies the claimant of the extension, and ends on the date on which the claimant responds to the request for additional information ([.33]).

Adverse benefit determinations—procedural considerations under final regs

A denial of a health claim, or an "adverse benefit determination," is broadly defined to include ([.34]):

- the denial of a benefit;

- the termination of a benefit;
- the reduction of a benefit; and
- the failure to provide or make payment (in whole or in part) for a benefit.

The definition also specifically encompasses determinations with respect to plan eligibility, compliance with utilization review procedures, and treatments considered experimental, investigational, not medically necessary, and not medically appropriate.

An adverse benefit determination includes, for plans providing disability benefits, a rescission of disability benefits coverage that has a retroactive effect (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time) ([.35]). For this purpose, the term “rescission” means a cancellation or discontinuance of coverage that has retroactive effect, except to the extent it is attributable to a failure to timely pay required premiums or contributions towards the cost of coverage.

Manner of notification of initial benefit determinations. Final rules provide the manner and content of notifications of both initial benefit determinations, and benefit determinations upon review. For initial determinations concerning urgent care, notification may be oral, so long as a written or electronic notification is furnished to the claimant no later than 3 days after the oral notification ([.36]). Written and electronic notifications (as discussed below) are also acceptable means of notification. As a practical matter, it may be difficult to respond in writing to an urgent care claim within the 72-hour time frame (or 24-hour time frame for urgent claims involving continuing treatments).

Written and electronic notifications. With respect to pre-service and post-service claims, notifications may not be provided orally—electronic notice or written notice is required ([.37]). In the event electronic notice is furnished, the notices must comport with the specifications set forth in ERISA Reg. §2520.104b-1(c)(1). This regulation, among other things, requires plan administrators to take all appropriate steps to ensure that the system furnishing the documents results in actual receipt.

Content of all notifications. Electronic or written notifications must contain specific information, "set forth in a manner calculated to be understood by the claimant" ([.38]). Such information includes:

- the specific reason(s) why the claim is being denied;
- reference to the plan provision(s) on which the determination is based;
- a description of any additional material necessary for the claimant to present a "clean claim" and an explanation as to why this information is necessary;
- a description of the plan's review procedures and the applicable time limits, including a statement that the participant has a right to bring a civil action under ERISA Sec. 502(a);
- a copy of any internal rule, guideline or protocol relied upon in making the adverse determination. In lieu thereof, the notice may state that such information is available free of charge upon request; and
- with respect to medical necessity or experimental treatment determinations (or similar determinations) an explanation of the scientific or clinical judgment relied upon for making the determination. In lieu there, the notice may state that such information is available free of charge upon request.

Adverse benefit determinations on disability benefit claims must contain the following ([.40]):

- a discussion of the decision, including the basis for disagreeing with any disability determination by the Social Security Administration (SSA), by a treating physician, or other third party disability payor, to the extent that the plan did not follow those determinations presented by the claimant;
- if the adverse benefit decision is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant’s medical circumstances, or a statement that such explanation will be provided free of charge upon request;

- the internal rules, guidelines, protocols, standards or other similar criteria of the plan that were used in denying the claim (or a statement that these do not exist); and
- a statement that the claimant is entitled to receive, upon request, relevant documents.

Culturally and linguistically appropriate notices. Benefit denial notices for disability benefits must be provided in a culturally and linguistically appropriate manner in certain situations. The final rule for disability benefits essentially adopts the ACA standard for group health benefit notices. Specifically, if a disability claimant's address is in a county where 10 percent or more of the population is literate only in the same non-English language, benefit denial notices must include a prominent statement in the relevant non-English language about the availability of language services. The plan also must provide a verbal customer assistance process in the non-English language and provide written notices in the non-English language upon request. ([.50]).

Adverse benefit determinations—practical considerations

There are many reasons why a health plan administrator will deny a claim for reimbursement or payment of expenses (see also ¶10,410, ¶10,415, and ¶10,420). These include:

- **The services may not be covered by the benefit plan**; for example, experimental surgery or treatments, though difficult to define, are often disallowed expenses when they have not been proven to be effective ([.60]). Many employers and insurers rely on medical consultants or experts to determine the experimental nature of certain treatments. Certain plans exclude as covered services treatment for mental and nervous diagnoses ([.65]) and custodial care ([.70]) or other expenses ([.75]). However, when the definition of terms, such as mental illness, is ambiguous, the plan could not impose a limitation ([.80]). An exclusion for work-related accidents did not apply since the policy terms are interpreted in their ordinary and popular sense and plan terms that are ambiguous are interpreted in favor of the insured ([.85]).
- **The plan maximum benefit level has been reached**; for example, the plan may already have paid for the maximum 30 days of inpatient treatment for substance abuse. See ¶10,335. Despite a plan limit on reimbursement for charges for confinement in an intensive care unit, a plan was responsible for payment of related charges, such as transfusions, for a patient confined to an ICU ([.90]).
- **The individual may not be eligible** under the plan ([.95]) (for example, the person may not have worked for the employer the required 90 days or a dependent may not be a full-time student). Partial denial for charges above the reasonable and customary limits may preclude consideration of the entire benefit amount. Coverage may be limited to full-time employees. An individual who worked less than the 30-hour per week requirement for a company was not a full-time employee entitled to benefits, even though he had enrolled and paid premiums ([.100]).
- **Plans may limit coverage for dependents.** A plan that covered expenses for an adopted child's birth did not need to cover the prenatal or other medical expenses of the birth mother ([.105]). An insurance policy did not need to cover the expenses of a participant's newborn since the participant had only elected single coverage and not family coverage ([.110]).
- A claim may be denied if the claimant has a **preexisting condition** that precludes coverage until a specified exclusion period has passed ([.115]); for example, a person who has in the past been treated for cancer would not be reimbursed for subsequent cancer treatments until a designated period passes during which the person has no treatment for that condition. See also discussion at ¶10,420 and 10,555. Following satisfaction of the exclusion period, however, the claims for cancer-related treatment would be considered eligible expenses under the plan. A preexisting conditions clause may not be valid if not conspicuous enough in the summary plan description. It must be clear, plain, and conspicuous enough to negate a layman's reasonable expectation of health coverage and should have a heading to identify it

([.120]). Whether the participant knew of the condition before enrolling in the plan can affect coverage status as can misrepresentation by either an employee or an insurance agent ([.125]). Waiver of an exclusion for preexisting conditions does not constitute a waiver for all excluded services ([.130]). In addition, the Health Insurance Portability and Accountability Act limits preexisting condition periods in group health plans.

- Plans may deny benefits when a **participant makes a material misrepresentation** on an insurance application ([.135]).
- Services may be denied either because they are **not of a medical nature** ([.140]) **or the medical need for the services cannot be demonstrated** ([.145]). However, when the medical necessity is supported by five criteria in a plan document, an insurer must pay for proposed treatment ([.150]). In questions of medical necessity, plan administrators must examine the entire medical record to avoid abuse of discretion ([.155]). However, the Tenth Circuit has ruled that an insurance plan did not arbitrarily and capriciously deny residential medical health benefits to a participant's dependent, despite his treating physician's determination that residential treatment was required, because sufficient evidence also existed to support the plan's approval of less restrictive, outpatient treatment. The court so held despite the fact that the plan required a physician's face-to-face evaluation for a medical diagnosis, but then disregarded the same physician's evaluation for purposes of continued coverage ([.157]). Although custodial care is often a noncovered expense since there may be no medical need for the service, constant skilled care is not considered primarily custodial care ([.160]). Also, coverage may not be denied based on lack of medical need where the participant is not notified of the right to present evidence of such need, as required by plan procedure ([.165]).
- Claims for services may be denied if there has been **no premium payment, which has caused the coverage to lapse** ([.170]). An employer had no cause of action against an insurance agent after the insurance company that the agent had recommended refused to pay an employee's claims for medical care ([.175]). However, when ambiguously worded, the plan insurer may be liable for expenses incurred after the policy ends which arose from an injury suffered during the term of the policy ([.180]).
- **Claims for expenses incurred while engaging in criminal activities** may be denied when the plan contains a payment exclusion ([.185]).

Untimely submissions

Many policies provide time limits for submitting proof-of-claims and may even state that benefits will be forfeited in the event of an untimely submission of proof ([.187]). However, a Court of Appeals has ruled that an insurer must show *actual prejudice* resulting from an untimely submission of proof in order to deny payment—even if the plan language regarding the forfeiture is clear ([.190]). The final regulations issued in 2000 do not address time limits for submitting proof-of-claims.

Appeal procedures under final rules

Once an adverse benefit determination has been made, the final regulations require plans to provide participants and beneficiaries a "full and fair review" of their claims ([.200]). With respect to group health plans, this means that, at a minimum, the plan must ([.205]):

- provide at least 180 days after receipt of a notification of an adverse benefit determination within which to appeal;
- provide claimants the opportunity to submit written comments and documents pertaining to the claim;
- provide to a claimant upon request and free of charge all records relevant to the claim;
- afford no deference to the initial determination (in other words, conduct a "de novo" review) and appoint

an appropriate, impartial fiduciary to conduct the appeal. In this regard, the fiduciary must not be a subordinate of the person who made the initial benefit determination. However, the plan need not go outside of the plan to retain the individual;

- identify any medical or vocational experts relied upon in connection with the claim; and
- provide "independent" medical reviews in cases involving (in whole or in part) medical judgment, such as whether a treatment or drug is experimental or whether treatment is medically necessary. Again, the plan need not retain an expert outside of the plan. Rather, any health care professional "with appropriate training and experience" may review the claim, so long as that person was not consulted during the initial benefit determination process. Further, the expert must not be a subordinate of the person who made the initial benefit determination.

The claims procedures of a plan providing disability benefits will not, with respect to claims for such benefits, be deemed to provide a claimant with a reasonable opportunity for a full and fair review of a claim and adverse benefit determination unless, in addition to complying with ERISA Reg. §2560.503-1(h)(2)(ii) through (iv) and ERISA Reg. §2560.503-1(h)(3)(i) through (v), the claims procedures ([.210]):

- allow a claimant to review the claim file and to present evidence and testimony as part of the disability benefit claims and appeals process;
- provide that, before the plan can issue an adverse benefit determination, the plan administrator must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan (or at the direction of the plan) in connection with the claim; and
- provide that before the plan can issue an adverse benefit determination based on a new or additional rationale, the plan administrator must provide the claimant, free of charge, with the rationale.

Expedited review procedures for urgent care claims. Health plans must also provide an expedited review process for urgent care claims in order to comply with the "full and fair review" requirement ([.220]). In addition, the plan must:

- allow the claimant to submit his/her claim either orally or in writing;
- transmit all relevant information, including the benefit determination on review, via telephone, fax, or "similarly expeditious method." The benefit determination upon review must be made "as soon as possible," but in no event later than 72 hours after receipt of the request for review ([.225].)

Appeals involving pre-service claims. With respect to pre-service claims, the regulations distinguish between plans that provide one level of appeal and those that provide two. [Note: under the regulations, a plan may not mandate more than two levels of review. After that time, the claimant must be allowed to bring an action under ERISA Sec. 502(a). Further, both voluntary and mandatory arbitration are allowed, subject to several restrictions.]

If a plan provides only one level of review, plans must respond to an appeal within "a reasonable time frame," but no later than 30 days after receipt of the request for review ([.2251]). However, in the event the plan provides for two levels of review, the response to *one of the appeals* must be no later than 15 days after receipt of the request for review. Note that the regulations do not state which review (i.e., the first or second) must have a 15-day turnaround time. Rather, the language is "*with respect to any one of the appeals.*" This is one aspect of the regulations that may require further guidance.

Appeals involving post-service claims. With respect to post-service claims, plans with one level of review must decide the appeal no later than 60 days after receipt of the request for review ([.2256]). Plans that provide two levels of review, must decide "*any one of such two appeals*" no later than 30 days after receipt of the request for review.

Appeals of disability claims. Disability plans must decide appeals within 45 days, although extensions of time are allowed. This rule applies regardless of whether the plan has one or two levels of review ([.2257]).

Calculating the time periods. The time period within which appeals must be decided begins at the time an appeal is filed "in accordance with the reasonable procedures of a plan, without regard to whether all the information necessary to make a benefit determination on review accompanies the filing" ([.2258]). If the claimant fails to submit all necessary materials for deciding the appeal, the plan administrator may request an extension of time. In this event, the time period tolls from the date on which the notice to extend time is sent to the claimant until the date on which the claimant responds to the request for additional information.

Notification of benefit determination on appeal. Written or electronic notification of a decision on review is acceptable ([.2259]). However, specific information is required, and, in the event of an adverse determination, plan administrators may be required to furnish a claimant with detailed records and documentation. Some of the notification requirements include:

- The reason for any adverse determination must always be specified.
- The notice must refer to the specific plan provision relied upon in making a determination.
- The claimant must be informed that he/she is entitled to receive, free of charge, all relevant records, including internal rules or protocols. ["Relevant" is defined under the regulations. See ERISA Reg. §2560.503-1(m)(8).]
- If the adverse benefit determination is based on a medical necessity or experimental treatment or similar exclusion or limit, either an explanation of the scientific or clinical judgment for the determination, applying the terms of the plan to the claimant's medical circumstances, or a statement that such explanation will be provided free of charge upon request.

Copy of audio recording. ERISA Sec. 503 and ERISA Reg. §2560.503-1 require a plan fiduciary to provide, upon a claimant's request, a copy of an audio recording and transcript of a telephone conversation between the claimant and a representative of the plan's insurer relating to an adverse benefit determination, according to a DOL information letter issued in June 2021. Guidance was sought about a claimant's right to receive a recording of a telephone conversation because the claimant's request for the recording was denied. According to information provided to EBSA, the stated reasons for the denial of the request for the audio recording were that the actual recording was distinct from the notes made available to the claimant that contemporaneously documented the content of the recorded conversation, and that became part of the "claim activity history through which [the insurer] develops, tracks and administers the claim." The plan fiduciary's denial stated that the "recordings are for 'quality assurance purposes,'" and "are not created, maintained, or relied upon for claim administration purposes, and therefore are not part of the administrative record."

The DOL concluded that a recording or transcript of a conversation with a claimant would not be excluded from the requirements under ERISA Reg. Sec. 2560.503-1 to disclose relevant "documents, records, and other information" merely because the plan or claims administrator does not include the recording or transcript in its administrative record; does not treat the recording or transcript as part of the claim activity history through which the insurer develops, tracks, and administers the claim; or because the recording or transcript was generated for quality assurance purposes.

ERISA Sec. 503 requires every employee benefit plan to "afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim." The DOL noted that the implementing regulations require that the claims procedures of an employee benefit plan will not provide a reasonable opportunity for a full and fair review of a denied claim, unless, among other things, "the claims procedures provide that a claimant shall be provided, upon request . . . copies of, all documents, records, and other information relevant to the claimant's claim for benefits." Among other things, the regulations provide that, for this purpose, a document, record, or other information is " 'relevant' to a claimant's claim" if the document, record, or other information "was … generated in the course of making the benefit determination," even if it was not "relied upon in making the benefit determination." Thus, the DOL explained that it was immaterial whether information was "not created, maintained, or relied upon for claim administration purposes."

As to the assertion that a claim that a recording was not required to be disclosed because it was generated for quality assurance purposes, the regulations state that information is relevant for purposes of the disclosure requirement if it "demonstrates compliance with the administrative processes and safeguards required pursuant to paragraph (b)(5)" of the regulation. Therefore, the fact that a recording was made for quality assurance purposes would support it being subject to a disclosure request for relevant "documents, records, and other information," according to the DOL.

Finally, the DOL observed that nothing in the regulation requires that "relevant documents, records, or other information" consist only of paper or written materials. On the contrary, the Department has recognized that an audio recording can be part of a claimant's administrative record.

Preemption of state laws. State laws that do not "prevent the application" of rules are not preempted ([.230]). In addition, state laws that mandate independent external reviews of medical claims are specifically not preempted.

The Seventh Circuit Court of Appeals has held that a healthcare provider's state law claims against a welfare benefit plan that erroneously represented that a participant's medical expenses would be covered are not preempted by ERISA ([.2301]). In *Franciscan,* oral representations were made by the welfare plan assuring the healthcare provider that a participant's treatment would be covered. After submitting a claim for benefits, the healthcare provider discovered that the participant's coverage had been terminated one month prior to the submission for failure to pay COBRA premiums.

The healthcare provider filed Wisconsin state law claims of negligent misrepresentation and estoppel, and the case was removed to district court. When the case was dismissed and the healthcare provider appealed, the appellate court stated that, although the healthcare provider had taken an assignment of benefits from the participants, it did not effectively stand in her shoes, and the healthcare provider was not an ERISA beneficiary. The court found that the healthcare provider had not filed suit as the participant's assignee, although it could have. Its claim was, instead, based upon oral misrepresentations made by the plan directly to the provider. The court added that the negligent misrepresentation and estoppel claims were based on duties imposed by Wisconsin state law that were entirely separate from ERISA or the plan terms.

The court left open the questions of whether or not the provider's claim would be vulnerable to an assertion of conflict preemption.

The Moran decision. In *Rush Prudential HMO, Inc. v. Moran*, the U.S. Supreme Court held that ERISA did not preempt an Illinois law allowing for an independent external review to resolve disputes over the "medical necessity" of medical treatments that a patient's primary care doctor has recommended ([.2303]). The end result of the Court's decision is that state independent review laws will control, as long as they don't create a new cause of action or provide a remedy beyond the benefits otherwise available under a plan.

In *Moran*, an HMO that contracted to provide health care benefits for ERISA plans provided coverage to Debra Moran through her husband's employer. To correct a shoulder injury, Moran's primary care physician told her that she needed an "unconventional" and somewhat expensive surgery, which was to be performed by a doctor that was not affiliated with the HMO. The HMO denied both Moran's request for approval of the procedure and her subsequent appeal. In the meantime, Moran had the surgery, paying for it at her own expense. After the HMO refused to provide an independent physician's review of its decision, Moran sued under the Illinois HMO law, which mandated such an independent review. An independent medical review ordered by the state court determined that the treatment had been "medically necessary." Eventually, the case wound its way up to the Supreme Court.

According to the Court, the Illinois HMO Act is directed towards the insurance industry and thus is considered an insurance regulation. Although the HMO provides healthcare in addition to insurance, "nothing in the [ERISA] saving clause requires an either-or choice between healthcare and insurance," the Court said. In the year before it passed ERISA, Congress recognized that HMOs are risk-bearing organizations subject to state regulation, the Court pointed out, noting that this conception has not changed in the interim and that at least 40 states regulate HMOs primarily through state insurance departments. The Court added that, just because the HMO arranged for

contracts with its affiliated physicians under which, the HMO claimed, any risk was borne by a third-party insurer, that reinsurance arrangement did not mean that the HMO was no longer in the insurance business.

The court also found that the state law's independent review requirement, in cases where an HMO's denial of coverage created an internal disagreement, regulated "an integral part of the policy relationship between the insurer and insured," and that the law was aimed at a "practice...limited to entities within the insurance industry," two factors that spared the state HMO law from ERISA preemption.

Deemed exhaustion. Except for *de minimis* violations that meet certain conditions, in the case of a claim for disability benefits, if a plan fails to strictly adhere to all of the requirements of ERISA Reg. §2560.503-1, a claimant will be deemed to have exhausted the administrative remedies available under the plan and will be entitled to pursue any available remedies under ERISA Sec. 502 on the basis that the plan has failed to provide a reasonable claims procedure that would yield a decision on the merits of the claim ([.2304]). If a claimant chooses to pursue remedies under ERISA Sec. 502 under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

Decisions about denial based on discretion

Ultimately, a participant may initiate a lawsuit to decide whether the plan should pay a claim. Depending on the amount of discretion accorded the administrator in interpreting a claim, the court will decide whether the denial of benefits constituted an abuse of discretion or review the facts *de novo* and make a decision on coverage ([.231]) (see ¶130,090). In order for a district court to properly apply an arbitrary and capricious standard of review to a denial of coverage for experimental treatment, the court must have a complete record, including a thorough explanation by the administrator of the denial ([.235]). When a fiduciary who administers a health plan has a conflict of interest that affects its decision-making when exercising discretion, the conflict must be considered in determining if there was an abuse of discretion. One court has ruled that an insurer seeking to make a profit is always in direct conflict with its role as a fiduciary when it pays benefits from its own assets, rather than a trust ([.240]).

If there is no conflict of interest, the proper standard of review is whether the administrator abused its discretion ([.245]).

Supreme Court on review of conflict-of-interest cases. A plan administrator that both evaluates and pays benefits claims operates under a conflict of interest in making discretionary benefit determinations, the U.S. Supreme Court has ruled. The conflict does not change the standard of review of a benefits denial from deferential to *de novo*, but the conflict should be weighed as a factor in determining whether there was an abuse of discretion ([.247]). A conflict of interest should prove more important where there is a higher likelihood that it affected the benefits decision, such as where an insurance company administrator has a history of biased claims administration. The conflict would prove less important, the court explained, "where the administrator has taken active steps to reduce potential bias and to promote accuracy, for example, by walling off claims administrators from those interested in firm finances . . . ."

Damages for denial of benefits

ERISA Sec. 502(a) contains nothing to allow courts to fashion a federal common law remedy to grant employees the right to recover punitive or extracontractual damages ([.250]).

Policy limitations

A health plan or insurance policy can limit coverage in several ways. The plan can establish dollar maximums on what it will reimburse (see annual or out-of-pocket maximums at ¶10,310), exclude certain kinds of care from coverage, subject to state and federal mandates (see ¶10,415), or exclude coverage for certain people (for example, dependents after certain ages, employees who do not work full-time, non-married partners, or dependents' children— see discussion of dependents at ¶10,105). Any exclusion must not discriminate,

especially against persons with disabilities (see discussion of Americans with Disabilities Act at ¶10,060).

Appeals process under the Patient Protection and Affordable Care Act

For plan years beginning on or after September 23, 2010, group health plans and health insurers must implement an effective process for appeals of coverage determinations and claims. This appeals process must include, at a minimum, the following:

- an established internal claims appeal process;
- a notice to participants, in a "culturally and linguistically appropriate manner," of available internal and external appeals processes, including the availability of an office of health insurance consumer assistance or ombudsman to assist with the appeals processes; and
- a provision allowing an enrollee to review his or her file, to present evidence and testimony as part of the appeals process, and to receive continued coverage during the appeals process ([.300]).

Internal review requirements. Pursuant to interim final regulations, plans must adhere to six new requirements, in addition to those found in the existing DOL claims procedure regulation (see discussion above), in order to implement the “effective” internal claims and appeals process required under the ACA ([.305]).

Adverse benefit determination. The definition of an adverse benefit determination is broader than the definition in the DOL claims procedure regulation, in that an adverse benefit determination for purposes of the final regulations also includes a rescission of coverage ([.315]). An adverse benefit determination eligible for internal claims and appeals processes under the regulations includes a denial of, reduction of, termination of, or failure to provide or make a payment for a benefit, including the following:

- a determination of an individual's eligibility to participate in a plan or health insurance coverage;
- a determination that a benefit is not a covered benefit;
- the imposition of a preexisting condition exclusion, source-of-injury exclusion, network exclusion, or other limitation on otherwise covered benefits; or
- a determination that a benefit is experimental, investigational, or not medically necessary or appropriate.

72-hour notice. For urgent care claims (as defined in existing DOL claims procedure regulations), the regulations provide that a plan must notify a claimant of a benefit determination (whether adverse or not) as soon as possible, but not later than 72 hours after the receipt of the claim by the plan or health insurance coverage, unless the claimant fails to provide sufficient information to determine whether benefits are covered or payable ([.320]).

The June 2011 amendments to the interim final rules permit plans and issuers to follow the original rule in the DOL claims procedure regulation (requiring decisionmaking in the context of preservice urgent care claims as soon as possible, but in no event later than 72 hours, consistent with the medical exigencies involved), provided that the plan or issuer defers to the attending provider with respect to the decision as to whether a claim constitutes "urgent care." At the same time, the Departments underscore that the 72-hour timeframe remains only an outside limit and that, in cases where a decision must be made more quickly based on the medical exigencies involved, the requirement remains that the decision should be made sooner than 72 hours after receipt of the claim.

Full and fair review. The regulations provide additional criteria to ensure that a claimant receives a full and fair review. In addition to complying with the requirements of the existing DOL claims procedure regulation, a plan must provide the claimant, free of charge, with any new or additional evidence considered by the plan in connection with the claim. Such evidence must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond. Also, before the plan can issue an adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale. The

rationale also must be provided as soon as possible and sufficiently in advance of the date on which the notice of adverse benefit determination on review is required ([.330]).

Conflict of interest. New criteria are provided with respect to avoiding conflicts of interest. The plan or issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Thus, decisions regarding hiring, compensation, termination, promotion, or other similar matters must not be made based upon the likelihood that the individual will support a denial of benefits. For example, a plan or issuer cannot provide bonuses based on the number of denials made by a claims adjudicator. Similarly, a plan or issuer cannot contract with a medical expert based on the expert's reputation for outcomes in contested cases, rather than based on the expert's professional qualifications ([.335]).

"Culturally appropriate." The ACA and the regulations require a plan to provide a notice to enrollees "in a culturally and linguistically appropriate manner." This provision applies to internal and external claims appeals processes. Plans and issuers are considered to provide relevant notices in a culturally and linguistically appropriate manner if notices are provided in a non-English language based on thresholds of the number of people who are literate in the same non-English language ([.340]).

A group health plan and a health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets the following requirements:

1. the plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that include answering questions in any applicable non-English language and providing assistance with filing claims and appeals (including external review) in any applicable non-English language;
2. the plan or issuer must provide, upon request, a notice in any applicable non-English language; and
3. the plan or issuer must include in the English versions of all notices, a statement prominently displayed in any applicable non-English language clearly indicating how to access the language services provided by the plan or issuer ([.345]).

With respect to an address in any United States county to which a notice is sent, a non-English language is an applicable non-English language if ten percent or more of the population residing in the county is literate only in the same non-English language, as determined in guidance published by the Secretary.

In addition, a plan must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved. This includes the date of service, the health care provider, the claim amount (if applicable), and a statement describing the availability, upon request, of the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning ([.350]).

Additionally, the plan or issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal ([.355]). Finally, the plan or issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman to assist enrollees with the internal claims and appeals and external review processes ([.360]).

Failure to comply. If a plan fails to strictly adhere to all the requirements of the internal claims and appeals process, the claimant is deemed to have exhausted the internal claims and appeals process, with the exception explained below. Upon such a such a failure, the claimant may initiate an external review and pursue any available remedies under applicable law, such as judicial review ([.370]).

The internal claims and appeals process will not be deemed exhausted based on *de minimis* violations that do not cause, and are not likely to cause, prejudice or harm to the claimant so long as the plan or issuer demonstrates that the violation was for good cause or due to matters beyond the control of the plan or issuer

and that the violation occurred in the context of an ongoing, good faith exchange of information between the plan and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the plan or issuer. The claimant may request a written explanation of the violation from the plan or issuer, and the plan or issuer must provide such explanation within 10 days, including a specific description of its bases, if any, for asserting that the violation should not cause the internal claims and appeals process to be deemed exhausted ([.380]).

Options for external reviews. Group health plans and insurers have two options regarding the implementation of external reviews:

1. Plans and insurers must comply with state external review requirements that are binding and at a minimum include the consumer protections in the Uniform External Review Model Act from the National Association of Insurance Commissioners (NAIC); or
2. If state requirements do not meet the minimums or if the plan is self-funded and not subject to state insurance regulations, then the plan must implement an external review process that is similar to that in the Uniform External Review Model Act and that meets standards established by the Department of Health and Human Services ([.390]).

Final regulations provide a basis for determining when plans must comply with a state external review process and when they must comply with the federal external review process.

State external review process. For health insurance coverage, if a state external review process includes, at a minimum, the consumer protections in the NAIC Uniform Model Act in place on July 23, 2010, then the issuer must comply with the applicable state external review process and not with the federal external review process. In such a case, to the extent that benefits under a group health plan are provided through health insurance coverage, the issuer is required to satisfy the obligation to provide an external review process, so the plan itself is not required to comply with either the state external review process or the federal external review process ([.400]).

The regulations do not preclude a state external review process from applying to and being binding on a self-insured group health plan under some circumstances. While the preemption provisions of ERISA ordinarily would prevent a state external review process from applying directly to an ERISA plan, ERISA preemption does not prevent a state external review process from applying to some self-insured plans, such as nonfederal governmental plans and church plans not covered by ERISA preemption, and multiple employer welfare arrangements, which can be subject to both ERISA and state insurance laws. A state external review process could apply to such plans if the process includes, at a minimum, the consumer protections in the NAIC Uniform Model Act ([.405]).

Any plan not subject to a state external review process must comply with the federal external review process ([.410]).

Minimum standards for state external review processes. For a state external review to apply instead of the federal process, the state external review process must include the following elements from the NAIC Uniform Model Act ([.420]):

- Provide for the external review of adverse benefit determinations that are based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.
- Require issuers to provide effective written notice to claimants of their rights.
- If exhaustion of internal appeals is required prior to external review, exhaustion must be unnecessary if – (a) the issuer (or plan) waives the exhaustion requirement; (b) the issuer (or plan) is considered to have exhausted the internal appeals process by failing to comply with the requirements of the internal appeals process except those failures that are based on de minimis violations that do not cause, and are not likely to cause, prejudice or harm to the claimant or (c) the claimant simultaneously requests an expedited internal appeal and an expedited external review.

- Provide that the issuer must pay the cost of an independent review organization (IRO) for conducting the external review.
- Not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review (for example, a $500 minimum claims threshold).
- Allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.
- Provide that an independent review organization will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process.
- Provide for maintenance of a list of approved independent review organizations qualified to conduct the review based on the nature of the health care service that is the subject of the review.
- Provide that any approved IRO has no conflicts of interest that will influence its independence.
- Allow the claimant to submit to the IRO in writing additional information that the IRO must consider when conducting the external review and require that the claimant is notified of such right to do so.
- Provide that the decision is binding on the plan or issuer, as well as the claimant, except to the extent that other remedies are available under state or federal law.
- Provide that, for standard external review, within no more than 45 days after the receipt of the request for external review by the IRO, the IRO must provide written notice to the issuer and the claimant of its decision to uphold or reverse the adverse benefit determination.
- Provide for an expedited external review in certain circumstances and, in such cases, the state process must provide notice of the decision as expeditiously as possible, but not later than 72 hours after the receipt of the request.
- Require that issuers include a description of the external review process in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to claimants.
- Maintain written records and make them available upon request to the state, substantially similar to section 15 of the NAIC Uniform Model Act.
- Follow procedures for external review of adverse benefit determinations involving experimental or investigational treatment, substantially similar to what is set forth in the NAIC Uniform Model Act.

Federal external review process. A plan (including a multi state plan) or issuer not subject to an applicable state external review process must provide an effective federal external review process (except a plan under which benefits are provided by health insurance issuer covered by the state rules that need not comply with either the federal or state process). In the case of health insurance coverage offered in connection with a group health plan, if either the plan or the issuer complies with the federal external review process, the obligation to comply with the federal process is satisfied for both the plan and the issuer with respect to the health insurance coverage ([.430]).

Under the federal external review process, the process requirements generally apply to any rescission of coverage, or to any adverse benefit determination (including a final internal adverse benefit determination). However, a denial, reduction, termination, or a failure to provide payment for a benefit based on a determination that a participant or beneficiary fails to meet the requirements for eligibility under the terms of a group health plan is not eligible for the external review process under this process ([.432]).

A group health plan or health insurance issuer must allow a claimant to file a request for an external review with the plan or issuer if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. Within five business days following the date of receipt of the external review request, the group health plan or health insurance issuer must complete a

preliminary review of the request. Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. The group health plan or health insurance issuer must assign an accredited Independent Review Organization to conduct the external review ([.433]).

Scope of external review. Interim final regulations issued in October 2021 expand the scope of adverse benefit determinations eligible for external review to include determinations that involve whether a plan or issuer is complying with the surprise billing and cost-sharing protections under the No Surprises Act and its implementing regulations ([.435]). The regulations also provide that grandfathered plans that are not otherwise subject to external review requirements will be subject to external review requirements for coverage decisions that involve whether a plan or issuer is complying with the surprise billing and cost-sharing protections under the No Surprises Act.

The regulations provide the following examples:

EXAMPLE 1

A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual C receives pre-stabilization emergency treatment in an out-of-network emergency department of a hospital. The group health plan determines that protections for emergency services under ERISA Reg. §2590.716-4 do not apply because the treatment did not involve “emergency services” within the meaning of ERISA Reg. §2590.716-4(c)(2)(i). C receives an adverse benefit determination and the plan imposes cost-sharing requirements that are greater than the requirements that would apply if the same services were provided in an in-network emergency department.

The plan’s determination that treatment received by C did not include emergency services involves medical judgment and consideration of whether the plan complied with ERISA Reg. §2590.716-4. Accordingly, the claim is eligible for external review.

EXAMPLE 2

A group health plan generally provides benefits for anesthesiology services. Individual D undergoes a surgery at an in-network health care facility and during the course of the surgery, receives anesthesiology services from an out-of-network provider. The plan decides the claim for these services without regard to the protections related to items and services furnished by out-of-network providers at in-network facilities under ERISA Reg. §2590.716-5. As a result, D receives an adverse benefit determination for the services and is subject to cost-sharing liability that is greater than it would be if cost sharing had been calculated in a manner consistent with the requirements of ERISA Reg. §2590.716-5.

In this example, whether the plan was required to decide the claim in a manner consistent with the requirements of ERISA Reg. §2590.716-5 involves considering whether the plan complied with ERISA Reg. §2590.716-5, as well as medical judgment, because it requires consideration of the health care setting and level of care. Accordingly, the claim is eligible for external review.

EXAMPLE 3

A group health plan generally provides benefits for services in an emergency department of a hospital or independent freestanding emergency department. Individual E receives emergency services in an out-of-network emergency department of a hospital, including certain post-stabilization services. The plan processes the claim for the poststabilization services as not being for emergency services under ERISA Reg. §2590.716-4(c)(2)(ii) based on representations made by the treating provider that E was in a condition to receive notice from the provider about cost-sharing and surprise billing protections for these services and

subsequently gave informed consent to waive those protections. E receives an adverse benefit determination and is subject to cost-sharing requirements that are greater than the cost-sharing requirements that would apply if the services were processed in a manner consistent with ERISA Reg. §2590.716-4.

In this example, whether E was in a condition to receive notice about the availability of cost-sharing and surprise billing protections and give informed consent to waive those protections involves medical judgment and consideration of whether the plan complied with the requirements under ERISA Reg. §2590.716-4(c)(2)(ii). Accordingly, the claim is eligible for external review.

EXAMPLE 4

Individual F gives birth to a baby at an in-network hospital. The baby is born prematurely and receives certain neonatology services from a nonparticipating provider during the same visit as the birth. F was given notice about cost-sharing and surprise billing protections for these services, and subsequently gave informed consent to waive those protections. The claim for the neonatology services is coded as a claim for routine post-natal services and the plan decides the claim without regard to the requirements under ERISA Reg. §2590.716-5(a) and the fact that those protections may not be waived for neonatology services under ERISA Reg. §2590.716- 5(b).

In this example, medical judgment is necessary to determine whether the correct code was used and compliance with ERISA Reg. §2590.716-5(a) and ERISA Reg. §2590.716- 5(b) must also be considered. Accordingly, the claim is eligible for external review.

EXAMPLE 5

A group health plan generally provides benefits to cover knee replacement surgery. Individual G receives a knee replacement surgery at an in-network facility and, after receiving proper notice about the availability of cost-sharing and surprise billing protections, provides informed consent to waive those protections. However, during the surgery, certain anesthesiology services are provided by an out-of-network nurse anesthetist. The claim for these anesthesiology services is decided by the plan without regard to the requirements under ERISA Reg. §2590.716-5(a) or to the fact that those protections may not be waived for ancillary services such as anesthesiology services provided by an out-of-network provider at an in-network facility under ERISA Reg. §2590.716- 5(b). G receives an adverse benefit determination and is subject to costsharing requirements that are greater than the cost-sharing requirements that would apply if the services were provided in a manner consistent with ERISA Reg. §2590.716-5(a) and ERISA Reg. §2590.716- 5(b).

In this example, consideration of whether the plan complied with the requirements in ERISA Reg. §2590.716-5(a) ERISA Reg. §2590.716- 5(b) is necessary to determine whether cost-sharing requirements were applied appropriately. Accordingly, the claim is eligible for external review.

State determinations. The Center for Consumer Information and Insurance Oversight (CCIIO) has issued preliminary determinations for states in regard to the implementation of the external health claims review process. The following 23 states meet the "strict standard" (*i.e.,* the 16 minimum consumer protections based on the NAIC Model Act (see discussion above)): Arkansas, California, Colorado, Connecticut, Hawaii, Idaho, Illinois, Iowa, Kentucky, Maine, Maryland, Nevada, New Jersey, New York, Oklahoma, Oregon, Rhode Island, South Carolina, South Dakota, Utah, Vermont, Virginia, and Washington.

The following ten states meet the "similar standard" (*i.e.,* similar standards to those outlined in the interim final rule): Arizona, Delaware, Indiana, Kansas, Michigan, Minnesota, New Mexico, North Carolina, Tennessee, and

Wyoming.

Seventeen states and the District of Columbia are subject to the HHS/independent review organization process: Alabama, Alaska, District of Columbia, Florida, Georgia, Louisiana, Massachusetts, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Pennsylvania, Texas, West Virginia, and Wisconsin ([.440]).

Standard external review procedures for self-insured plans. The procedures for *standard* external review for self-insured group health plans include the following ([.460]):

1. *Request for external review.* A group health plan must allow a claimant to file a request for an external review with the plan if the request is filed within four months after the date of receipt of a notice of an adverse benefit determination or final internal adverse benefit determination. If there is no corresponding date four months after the date of receipt of such a notice, then the request must be filed by the first day of the fifth month following the receipt of the notice.
2. *Preliminary review.* Within five business days following the date of receipt of the external review request, the group health plan must complete a preliminary review of the request to determine whether:
    a. The claimant is or was covered under the plan at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan at the time the health care item or service was provided;
    b. The adverse benefit determination or the final adverse benefit determination does not relate to the claimant's failure to meet the requirements for eligibility under the terms of the group health plan (e.g., worker classification or similar determination);
    c. The claimant has exhausted the plan's internal appeal process unless the claimant is not required to exhaust the internal appeals process under the interim final regulations; and
    d. The claimant has provided all the information and forms required to process an external review. Within one business day after completion of the preliminary review, the plan must issue a notification in writing to the claimant.
3. *Referral to Independent Review Organization.* The group health plan must assign an independent review organization (IRO) that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. Moreover, the plan must take action against bias and to ensure independence. Accordingly, plans must contract with at least two IROs by January 1, 2012, and with at least three IROs by July 1, 2012, for assignments under the plan and rotate claims assignments among them (or incorporate other independent unbiased methods for selection of IROs, such as random selection). In addition, the IRO may note be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.
4. *Reversal of plan's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final internal adverse benefit determination, the plan immediately must provide coverage or payment (including immediately authorizing or immediately paying benefits) for the claim.

Expedited external review procedures for self-insured plans. The procedures for *expedited* external review for self-insured group health plans include the following ([.470]):

1. *Request for expedited external review.* A group health plan must allow a claimant to make a request for an expedited external review with the plan at the time the claimant receives:
    a. An adverse benefit determination if the adverse benefit determination involves a medical condition of the claimant for which the timeframe for completion of an expedited internal appeal under the interim final regulations would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function and the

claimant has filed a request for an expedited external appeal; or

b. A final internal adverse benefit determination, if the claimant has a medical condition where the timeframe for completion of a standard external review would seriously jeopardize the life or health of the claimant or would jeopardize the claimant's ability to regain maximum function, or if the final internal adverse benefit determination concerns an admission, availability of care, continued stay, or health care item or service for which the claimant received emergency services, but has not been discharged from a facility.

2. *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan must determine whether the request meets the reviewability requirements set forth in paragraph 2 above for standard external review. The plan must immediately send a notice that meets the requirements set forth in paragraph 2 above for standard external review to the claimant of its eligibility determination.

3. *Referral to independent review organization.* Upon a determination that a request is eligible for external review following the preliminary review, the plan will assign an IRO pursuant to the requirements set forth in paragraph 3 above for standard review. The plan must provide or transmit all necessary documents and information considered in making the adverse benefit determination or final internal adverse benefit determination to the assigned IRO electronically or by telephone or facsimile or any other available expeditious method.

4. *Notice of final external review decision.* The plan's contract with the assigned IRO must require the IRO to provide notice of the final external review decision, in accordance with the requirements set forth in paragraph 3 above for standard review, as expeditiously as the claimant's medical condition or circumstances require, but in no event more than 72 hours after the IRO receives the request for an expedited external review. If the notice is not in writing, within 48 hours after the date of providing that notice, the assigned IRO must provide written confirmation of the decision to the claimant and the plan.

Voluntary compliance with state external review processes. States may choose to expand access to their state external review process to plans that are not subject to the applicable state laws, such as self-insured plans. Such plans may choose to voluntarily comply with the provisions of that state external review process. In such circumstances, while the interim enforcement safe harbor is in effect, the DOL and the IRS also will not take enforcement action against a plan that voluntarily complies with the provisions of a state external review process that would not otherwise be applicable or available ([.480]).

HHS authority to determine compliance. The Secretary of HHS has the authority to determine whether the external review process of a plan or insurer, which is in operation as of March 23, 2010 (the date of enactment of the Patient Protection and Affordable Care Act), is in compliance ([.490]).

Safe harbor for non-federal governmental plans. The Department of Health and Human Services (HHS) has established an enforcement safe harbor with respect to the content of the adverse benefit determinations and final internal adverse benefit determinations issued by non-federal governmental plans ([.500]). HHS will not enforce the requirement, under PHSA Sec. 2719, that non-federal governmental plans provide notice of the private right of action under ERISA.

Similarly, HHS will not enforce the requirement that non-federal governmental plans provide contact information for the EBSA or a state department of insurance. This safe harbor is applicable as long as such a plan provides contact information for member assistance provided by any third-party administrator or health insurance issuer that is hired by or contracts with the plan, and, if available, consumer assistance offered directly by the plan such as applicable member services, employee services, human relations or fiscal or personnel department, or consumer support services, if applicable.

Consumer assistance program. In states that do not have a consumer assistance program, non-federal governmental plans that seek to take advantage of this safe harbor must provide the contact information for

HHS' Health Insurance Assistance Team (HIAT). The contact information for HIAT is 888-393-2789.

Other requirements still apply. This guidance does not provide non-federal governmental plans with relief from any other requirements of the PHSA, including the requirement that they provide all other notices required by the Department of Labor claims procedure regulation. Furthermore, to the extent that a non-federal governmental plan purchases a fully-insured health insurance policy for its participants or beneficiaries, or to the extent that state departments of insurance provide services to these participants or beneficiaries, HHS expects that participants and beneficiaries will receive the required contact information for the state department of insurance (or any other applicable state department).

Model notices. The DOL has issued model notices that can be used to satisfy the disclosure requirements for the internal claims and appeals and external review processes. For the Model Notice of Adverse Benefit Determination, see ¶226,115. For the Model Notice of Final Internal Adverse Benefit Determination, see ¶226,116. For the Model Notice of Final External Review Decision, see ¶226,117.

Footnotes

.01 ERISA Reg. §2560.503-1(a) and (b).

.05 Preamble to IRS, EBSA, HHS interim final regulations (75 FR 43350, July 23, 2010).

.07 76 FR 37208, June 24, 2011.

.09 80 FR 72192, November 18, 2015.

.10 ERISA Reg. §2560.503-1(m)(6).

.12 Preamble to final rules; 65 FR 70246, ERISA Sec. 733.

.14 ERISA Reg. §2560.503-1(b)(2).

.15 ERISA Reg. §2560.503-1(b)(7).

.16 DOL information letter, February 27, 2019.

.17 ERISA Reg. §2560.503-1(f)(2)(i).

.18 ERISA Reg. §2560.503-1(m)(1).

.20 ERISA Reg. §2560.503-1(m)(1)(ii).

.21 ERISA Reg. §2560.503-1(m)(1)(iii).

.22 ERISA Reg. §2560.503-1(f)(2)(i).

.23 ERISA Reg. §2560.503-1(m)(2)(i).

.24 ERISA Reg. §2560.503-1(f)(2)(ii)(B).

.25 Preamble to final rules; 65 FR 70246.

.27 ERISA Reg. §2560.503-1(f)(iii)(A).

.28 ERISA Reg. §2560.503-1(m)(2).

.29 ERISA Reg. §2560.503-1(f)(2)(iii)(A).

.295 ERISA Reg. §2560.503-1(c)(1).

.30 ERISA Reg. §2560.503-1(f)(2)(iii)(B).

.31 ERISA Reg. §2560.503-1(m)(3).

.32 ERISA Reg. §2560.503-1(f)(3).

.33 ERISA Reg. §2560.503-1(f)(4).

.34 ERISA Reg. §2560.503-1(m)(4).

.35 ERISA Reg. §2560.503-1(m)(4)(ii).

.36 ERISA Reg. §2560.503-1(g)(2).

.37 ERISA Reg. §2560.503-1(g)(1).

.38 ERISA Reg. §2560.503-1(g)(1).

.40 ERISA Reg. §2560.503-1(g)(1)(vii).

.50 ERISA Reg. §2560.503-1(g)(1)(viii) and ERISA Reg. §2560.503-1(o).

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