or the application of the provision to persons not similarly situated or to dissimilar circumstances.

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§ 147.136 Internal claims and appeals and external review processes.

(a) *Scope and definitions*—(1) *Scope.* This section sets forth requirements with respect to internal claims and appeals and external review processes for group health plans and health insurance issuers that are not grandfathered health plans under § 147.140. Paragraph (b) of this section provides requirements for internal claims and appeals processes. Paragraph (c) of this section sets forth rules governing the applicability of State external review processes. Paragraph (d) of this section sets forth a Federal external review process for plans and issuers not subject to an applicable State external review process. Paragraph (e) of this section prescribes requirements for ensuring that notices required to be provided under this section are provided in a culturally and linguistically appropriate manner. Paragraph (f) of this section describes the authority of the Secretary to deem certain external review processes in existence on March 23, 2010 as in compliance with paragraph (c) or (d) of this section.

(2) *Definitions.* For purposes of this section, the following definitions apply—

(i) *Adverse benefit determination.* An *adverse benefit determination* means an adverse benefit determination as defined in 29 CFR 2560.503–1, as well as any rescission of coverage, as described in § 147.128 (whether or not, in connection with the rescission, there is an adverse effect on any particular benefit at that time).

(ii) *Appeal (or internal appeal).* An *appeal* or *internal appeal* means review by a plan or issuer of an adverse benefit determination, as required in paragraph (b) of this section.

(iii) *Claimant. Claimant* means an individual who makes a claim under this section. For purposes of this section, references to claimant include a claimant's authorized representative.

(iv) *External review. External review* means a review of an adverse benefit determination (including a final internal adverse benefit determination) conducted pursuant to an applicable State external review process described in paragraph (c) of this section or the Federal external review process of paragraph (d) of this section.

(v) *Final internal adverse benefit determination.* A *final internal adverse benefit determination* means an adverse benefit determination that has been upheld by a plan or issuer at the completion of the internal appeals process applicable under paragraph (b) of this section (or an adverse benefit determination with respect to which the internal appeals process has been exhausted under the deemed exhaustion rules of paragraph (b)(2)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision* means a determination by an independent review organization at the conclusion of an external review.

(vii) *Independent review organization (or IRO).* An *independent review organization* (or *IRO*) means an entity that conducts independent external reviews of adverse benefit determinations and final internal adverse benefit determinations pursuant to paragraph (c) or (d) of this section.

(viii) *NAIC Uniform Model Act.* The *NAIC Uniform Model Act* means the Uniform Health Carrier External Review Model Act promulgated by the National Association of Insurance Commissioners in place on July 23, 2010.

(b) *Internal claims and appeals process*—(1) *In general.* A group health plan and a health insurance issuer offering group or individual health insurance coverage must implement an effective internal claims and appeals process, as described in this paragraph (b).

(2) *Requirements for group health plans and group health insurance issuers.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements of this paragraph (b)(2). 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 internal claims and appeals process of this paragraph (b)(2), then the obligation to comply with this paragraph (b)(2) is satisfied for both the plan and the

issuer with respect to the health insurance coverage.

(i) *Minimum internal claims and appeals standards.* A group health plan and a health insurance issuer offering group health insurance coverage must comply with all the requirements applicable to group health plans under 29 CFR 2560.503–1, except to the extent those requirements are modified by paragraph (b)(2)(ii) of this section. Accordingly, under this paragraph (b), with respect to health insurance coverage offered in connection with a group health plan, the group health insurance issuer is subject to the requirements in 29 CFR 2560.503–1 to the same extent as the group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(2)(i) of this section, the internal claims and appeals processes of a group health plan and a health insurance issuer offering group health insurance coverage must meet the requirements of this paragraph (b)(2)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(2), an ''adverse benefit determination'' includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as the other provisions of this paragraph (b)(2), a plan or issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the plan's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after the receipt of the claim) continue to apply to the plan and issuer. For purposes of this paragraph (b)(2)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the plan or issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* A plan and issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the plan or issuer (or at the direction of the plan or issuer) 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 final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the plan or issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the plan administrator shall notify the claimant of the plan's benefit determination as soon as a plan acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) *Avoiding conflicts of interest.* In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the plan and 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. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* A plan and issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The plan and issuer must also comply with the additional requirements of this paragraph (b)(2)(ii)(E).

(*1*) The plan and issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including 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).

(*2*) The plan and issuer must provide to participants, beneficiaries and enrollees, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The plan or issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The plan and issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the plan's or issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The plan and issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The plan and issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (*1*) In the case of a plan or issuer that fails to strictly adhere to all the requirements of this paragraph (b)(2) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(2)(ii)(F)(*2*) of this section. Accordingly the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under section 502(a) of ERISA or under State law, as applicable, on the basis that the plan or issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim. If a claimant chooses to pursue remedies under section 502(a) of ERISA under such circumstances, the claim or appeal is deemed denied on review without the exercise of discretion by an appropriate fiduciary.

(*2*) Notwithstanding paragraph (b)(2)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) 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 of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(2)(ii)(F)(*1*) of this section on the basis that the plan met the standards for the exception under this paragraph (b)(2)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the plan shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* A plan and issuer subject to the requirements of this paragraph (b)(2) are required to provide continued coverage pending the outcome of an appeal. For this purpose, the plan and issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii), which generally provides that benefits for an ongoing course of treatment cannot be reduced or terminated without providing advance notice and an opportunity for advance review.

(3) *Requirements for individual health insurance issuers.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of this paragraph (b)(3).

(i) *Minimum internal claims and appeals standards.* A health insurance issuer offering individual health insurance coverage must comply with all the requirements of the ERISA internal claims and appeals procedures applicable to group health plans under 29 CFR 2560.503–1 except for the requirements with respect to multiemployer plans, and except to the extent those requirements are modified by paragraph (b)(3)(ii) of this section. Accordingly, under this paragraph (b), with respect to individual health insurance coverage, the issuer is subject to the requirements in 29 CFR 2560.503–1 as if the issuer were a group health plan.

(ii) *Additional standards.* In addition to the requirements in paragraph (b)(3)(i) of this section, the internal claims and appeals processes of a health insurance issuer offering individual health insurance coverage must meet the requirements of this paragraph (b)(3)(ii).

(A) *Clarification of meaning of adverse benefit determination.* For purposes of this paragraph (b)(3), an adverse benefit determination includes an adverse benefit determination as defined in paragraph (a)(2)(i) of this section. Accordingly, in complying with 29 CFR 2560.503–1, as well as other provisions of this paragraph (b)(3), an issuer must treat a rescission of coverage (whether or not the rescission has an adverse effect on any particular benefit at that time) and any decision to deny coverage in an initial eligibility determination as an adverse benefit determination. (Rescissions of coverage are subject to the requirements of § 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* The requirements of 29 CFR 2560.503–1(f)(2)(i) (which generally provide, among other things, in the case of urgent care claims for notification of the issuer's benefit determination (whether adverse or not) as soon as possible, taking into account the medical exigencies, but not later than 72 hours after receipt of the claim) continue to apply to the issuer. For purposes of this paragraph (b)(3)(ii)(B), a claim involving urgent care has the meaning given in 29 CFR 2560.503–1(m)(1), as determined by the attending provider, and the issuer shall defer to such determination of the attending provider.

(C) *Full and fair review.* An issuer must allow a claimant to review the claim file and to present evidence and testimony as part of the internal claims and appeals process. Specifically, in addition to complying with the requirements of 29 CFR 2560.503–1(h)(2)—

(*1*) The issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by the issuer (or at the direction of the issuer) 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 final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date; and

(*2*) Before the issuer can issue a final internal adverse benefit determination based on a new or additional rationale, the claimant must be provided, free of charge, with the rationale; the rationale must be provided as soon as possible and sufficiently in advance of the date on which the notice of final internal adverse benefit determination is required to be provided under 29 CFR 2560.503–1(i) to give the claimant a reasonable opportunity to respond prior to that date. Notwithstanding the rules of 29 CFR 2560.503–1(i), if the new or additional evidence is received so late that it would be impossible to provide it to the claimant in time for the claimant to have a reasonable opportunity to respond, the period for providing a notice of final internal adverse benefit determination is tolled until such time as the claimant has a reasonable opportunity to respond. After the claimant responds, or has a reasonable opportunity to respond but fails to do so, the issuer shall notify the claimant of the issuer's determination as soon as an issuer acting in a reasonable and prompt fashion can provide the notice, taking into account the medical exigencies.

(D) Avoiding conflicts of interest. In addition to the requirements of 29 CFR 2560.503–1(b) and (h) regarding full and fair review, the 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. Accordingly, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual (such as a claims adjudicator or medical expert) must not be made based upon the likelihood that the individual will support the denial of benefits.

(E) *Notice.* An issuer must provide notice to individuals, in a culturally and linguistically appropriate manner (as described in paragraph (e) of this section) that complies with the requirements of 29 CFR 2560.503–1(g) and (j). The issuer must also comply with the additional requirements of this paragraph (b)(3)(ii)(E).

(*1*) The issuer must ensure that any notice of adverse benefit determination or final internal adverse benefit determination includes information sufficient to identify the claim involved (including the date of service, the name of 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).

(*2*) The issuer must provide to participants and beneficiaries, as soon as practicable, upon request, the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning, associated with any adverse benefit determination or final internal adverse benefit determination. The issuer must not consider a request for such diagnosis and treatment information, in itself, to be a request for an internal appeal under this paragraph (b) or an external review under paragraphs (c) and (d) of this section.

(*3*) The issuer must ensure that the reason or reasons for the adverse benefit determination or final internal adverse benefit determination includes the denial code and its corresponding meaning, as well as a description of the issuer's standard, if any, that was used in denying the claim. In the case of a notice of final internal adverse benefit determination, this description must include a discussion of the decision.

(*4*) The issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal.

(*5*) The issuer must disclose the availability of, and contact information for,

any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793 to assist individuals with the internal claims and appeals and external review processes.

(F) *Deemed exhaustion of internal claims and appeals processes.* (*1*) In the case of an issuer that fails to adhere to all the requirements of this paragraph (b)(3) with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process of this paragraph (b), except as provided in paragraph (b)(3)(ii)(F)(*2*) of this section. Accordingly, the claimant may initiate an external review under paragraph (c) or (d) of this section, as applicable. The claimant is also entitled to pursue any available remedies under State law, as applicable, on the basis that the issuer has failed to provide a reasonable internal claims and appeals process that would yield a decision on the merits of the claim.

(*2*) Notwithstanding paragraph (b)(3)(ii)(F)(*1*) of this section, the internal claims and appeals process of this paragraph (b) 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 issuer demonstrates that the violation was for good cause or due to matters beyond the control of the issuer and that the violation occurred in the context of an ongoing, good faith exchange of information between the issuer and the claimant. This exception is not available if the violation is part of a pattern or practice of violations by the issuer. The claimant may request a written explanation of the violation from the issuer, and the 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 of this paragraph (b) to be deemed exhausted. If an external reviewer or a court rejects the claimant's request for immediate review under paragraph (b)(3)(ii)(F)(*1*) of this section on the basis that the issuer met the standards for the exception under this paragraph (b)(3)(ii)(F)(*2*), the claimant has the right to resubmit and pursue the internal appeal of the claim. In such a case, within a reasonable time after the external reviewer or court rejects the claim for immediate review (not to exceed 10 days), the issuer shall provide the claimant with notice of the opportunity to resubmit and pursue the internal appeal of the claim. Time periods for re-filing the claim shall begin to run upon claimant's receipt of such notice.

(G) *One level of internal appeal.* Notwithstanding the requirements in 29 CFR 2560.503–1(c)(3), a health insurance issuer offering individual health insurance coverage must provide for only one level of internal appeal before issuing a final determination.

(H) *Recordkeeping requirements.* A health insurance issuer offering individual health insurance coverage must maintain for six years records of all claims and notices associated with the internal claims and appeals process, including the information detailed in paragraph (b)(3)(ii)(E) of this section and any other information specified by the Secretary. An issuer must make such records available for examination by the claimant or State or Federal oversight agency upon request.

(iii) *Requirement to provide continued coverage pending the outcome of an appeal.* An issuer subject to the requirements of this paragraph (b)(3) is required to provide continued coverage pending the outcome of an appeal. For this purpose, the issuer must comply with the requirements of 29 CFR 2560.503–1(f)(2)(ii) as if the issuer were a group health plan, so that the issuer cannot reduce or terminate an ongoing course of treatment without providing advance notice and an opportunity for advance review.

(c) *State standards for external review*—(1) *In general.* (i) If a State external review process that applies to and is binding on a health insurance issuer offering group or individual health insurance coverage includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the issuer must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. In such a case, to the extent that benefits under a group health plan are provided through

health insurance coverage, the group health plan is not required to comply with either this paragraph (c) or the Federal external review process of paragraph (d) of this section.

(ii) To the extent that a group health plan provides benefits other than through health insurance coverage (that is, the plan is self-insured) and is subject to a State external review process that applies to and is binding on the plan (for example, is not preempted by ERISA) and the State external review process includes at a minimum the consumer protections in the NAIC Uniform Model Act, then the plan must comply with the applicable State external review process and is not required to comply with the Federal external review process of paragraph (d) of this section. Where a self-insured plan is not subject to an applicable State external review process, but the State has chosen to expand access to its process for plans that are not subject to the applicable State laws, the plan may choose to comply with either the applicable State external review process or the Federal external review process of paragraph (d) of this section.

(iii) If a plan or issuer is not required under paragraph (c)(1)(i) or (c)(1)(ii) of this section to comply with the requirements of this paragraph (c), then the plan or issuer must comply with the Federal external review process of paragraph (d) of this section, except to the extent, in the case of a plan, the plan is not required under paragraph (c)(1)(i) of this section to comply with paragraph (d) of this section.

(2) *Minimum standards for State external review processes.* An applicable State external review process must meet all the minimum consumer protections in this paragraph (c)(2). The Department of Health and Human Services will determine whether State external review processes meet these requirements.

(i) The State process must provide for the external review of adverse benefit determinations (including final internal adverse benefit determinations) by issuers (or, if applicable, plans) that are based on the issuer's (or plan's) requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

(ii) The State process must require issuers (or, if applicable, plans) to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.

(iii) To the extent the State process requires exhaustion of an internal claims and appeals process, exhaustion must be unnecessary where the issuer (or, if applicable, the plan) has waived the requirement; the issuer (or the plan) is considered to have exhausted the internal claims and appeals process under applicable law (including by failing to comply with any of the requirements for the internal appeal process, as outlined in paragraph (b)(2) of this section); or the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.

(iv) The State process provides that the issuer (or, if applicable, the plan) against which a request for external review is filed must pay the cost of the IRO for conducting the external review. Notwithstanding this requirement, a State external review process that expressly authorizes, as of November 18, 2015, a nominal filing fee may continue to permit such fees. For this purpose, to be considered nominal, a filing fee must not exceed $25, it must be refunded to the claimant if the adverse benefit determination (or final internal adverse benefit determination) is reversed through external review, it must be waived if payment of the fee would impose an undue financial hardship, and the annual limit on filing fees for any claimant within a single plan year must not exceed $75.

(v) The State process may not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review. Thus, the process may not impose, for example, a $500 minimum claims threshold.

(vi) The State process must 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.

(vii) The State process must provide that IROs will be assigned on a random

basis or another method of assignment that assures the independence and impartiality of the assignment process (such as rotational assignment) by a State or independent entity, and in no event selected by the issuer, plan, or the individual.

(viii) The State process must provide for maintenance of a list of approved IROs qualified to conduct the external review based on the nature of the health care service that is the subject of the review. The State process must provide for approval only of IROs that are accredited by a nationally recognized private accrediting organization.

(ix) The State process must provide that any approved IRO has no conflicts of interest that will influence its independence. Thus, the IRO may not own or control, or be owned or controlled by a health insurance issuer, a group health plan, the sponsor of a group health plan, a trade association of plans or issuers, or a trade association of health care providers. The State process must further provide that the IRO and the clinical reviewer assigned to conduct an external review may not have a material professional, familial, or financial conflict of interest with the issuer or plan that is the subject of the external review; the claimant (and any related parties to the claimant) whose treatment is the subject of the external review; any officer, director, or management employee of the issuer; the plan administrator, plan fiduciaries, or plan employees; the health care provider, the health care provider's group, or practice association recommending the treatment that is subject to the external review; the facility at which the recommended treatment would be provided; or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended.

(x) The State process allows the claimant at least five business days to submit to the IRO in writing additional information that the IRO must consider when conducting the external review, and it requires that the claimant is notified of the right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer (or, if applicable, the plan) within one business day of receipt by the IRO.

(xi) The State process must provide that the decision is binding on the plan or issuer, as well as the claimant except to the extent the other remedies are available under State or Federal law, and except that the requirement that the decision be binding shall not preclude the plan or issuer from making payment on the claim or otherwise providing benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits. For this purpose, the plan or issuer must provide benefits (including by making payment on the claim) pursuant to the final external review decision without delay, regardless of whether the plan or issuer intends to seek judicial review of the external review decision and unless or until there is a judicial decision otherwise.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the issuer (or, if applicable, the plan) and the claimant of its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) within no more than 45 days after the receipt of the request for external review by the IRO.

(xiii) The State process must provide for an expedited external review if the adverse benefit determination (or final internal adverse benefit determination) concerns an admission, availability of care, continued stay, or health care service for which the claimant received emergency services, but has not been discharged from a facility; or involves a medical condition for which the standard external review time frame would seriously jeopardize the life or health of the claimant or jeopardize the claimant's ability to regain maximum function. As expeditiously as possible but within no more than 72 hours after the receipt of the request for expedited external review by the IRO, the IRO must make its decision to uphold or reverse the adverse benefit determination (or final internal adverse benefit determination) and notify the claimant and the issuer (or, if applicable, the plan) of the determination. If the notice is not in writing, the

IRO must provide written confirmation of the decision within 48 hours after the date of the notice of the decision.

(xiv) The State process must require that issuers (or, if applicable, plans) include a description of the external review process in or attached to the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees, substantially similar to what is set forth in section 17 of the NAIC Uniform Model Act.

(xv) The State process must require that IROs maintain written records and make them available upon request to the State, substantially similar to what is set forth in section 15 of the NAIC Uniform Model Act.

(xvi) The State process follows procedures for external review of adverse benefit determinations (or final internal adverse benefit determinations) involving experimental or investigational treatment, substantially similar to what is set forth in section 10 of the NAIC Uniform Model Act.

(3) *Transition period for external review processes*—(i) Through December 31, 2017, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of PHS Act section 2719(b). Accordingly, through December 31, 2017, an applicable State external review process will be considered binding on the issuer or plan (in lieu of the requirements of the Federal external review process). If there is no applicable State external review process, the issuer or plan is required to comply with the requirements of the Federal external review process in paragraph (d) of this section.

(ii) An applicable State external review process must apply for final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided on or after January 1, 2018. The Federal external review process will apply to such internal adverse benefit determinations unless the Department of Health and Human Services determines that a State law meets all the minimum standards of paragraph (c)(2) of this section. Through December 31, 2017, a State external review process applicable to a health insurance issuer or group health plan may be considered to meet the minimum standards of paragraph (c)(2) of this section, if it meets the temporary standards established by the Secretary in guidance for a process similar to the NAIC Uniform Model Act.

(d) *Federal external review process.* A plan or issuer not subject to an applicable State external review process under paragraph (c) of this section must provide an effective Federal external review process in accordance with this paragraph (d) (except to the extent, in the case of a plan, the plan is described in paragraph (c)(1)(i) of this section as not having to comply with this paragraph (d)). 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 of this paragraph (d), then the obligation to comply with this paragraph (d) is satisfied for both the plan and the issuer with respect to the health insurance coverage. A Multi State Plan or MSP, as defined by 45 CFR 800.20, must provide an effective Federal external review process in accordance with this paragraph (d). In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied when a Multi State Plan or MSP complies with standards established by the Office of Personnel Management.

(1) *Scope*—(i) *In general.* The Federal external review process established pursuant to this paragraph (d) applies to the following:

(A) An adverse benefit determination (including a final internal adverse benefit determination) by a plan or issuer that involves medical judgment (including, but not limited to, those based on the plan's or issuer's requirements for medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit; its determination that a treatment is experimental or investigational; its determination whether a participant or beneficiary is entitled to a reasonable alternative standard for a reward under a wellness program; or its determination whether a plan or issuer is complying with the nonquantitative treatment

limitation provisions of Code section 9812 and §54.9812, which generally require, among other things, parity in the application of medical management techniques), as determined by the external reviewer. (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 or health insurance coverage is not eligible for the Federal external review process under this paragraph (d)); and

(B) A rescission of coverage (whether or not the rescission has any effect on any particular benefit at that time).

(ii) *Examples.* The rules of paragraph (d)(1)(i) of this section are illustrated by the following examples:

Example 1. (i) *Facts.* A group health plan provides coverage for 30 physical therapy visits generally. After the 30th visit, coverage is provided only if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Individual *A* seeks coverage for a 31st physical therapy visit. *A*'s health care provider submits a treatment plan for approval, but it is not approved by the plan, so coverage for the 31st visit is not preauthorized. With respect to the 31st visit, *A* receives a notice of final internal adverse benefit determination stating that the maximum visit limit is exceeded.

(ii) *Conclusion.* In this *Example 1,* the plan's denial of benefits is based on medical necessity and involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notification of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because it fails to make clear that the plan will pay for more than 30 visits if the service is preauthorized pursuant to an approved treatment plan that takes into account medical necessity using the plan's definition of the term. Accordingly, the notice of final internal adverse benefit determination should refer to the plan provision governing the 31st visit and should describe the plan's standard for medical necessity, as well as how the treatment fails to meet the plan's standard.

Example 2. (i) *Facts.* A group health plan does not provide coverage for services provided out of network, unless the service cannot effectively be provided in network. Individual *B* seeks coverage for a specialized medical procedure from an out-of-network provider because *B* believes that the procedure cannot be effectively provided in network. *B* receives a notice of final internal adverse benefit determination stating that the claim is denied because the provider is out-of-network.

(ii) *Conclusion.* In this *Example 2,* the plan's denial of benefits is based on whether a service can effectively be provided in network and, therefore, involves medical judgment. Accordingly, the claim is eligible for external review under paragraph (d)(1)(i) of this section. Moreover, the plan's notice of final internal adverse benefit determination is inadequate under paragraphs (b)(2)(i) and (b)(2)(ii)(E)(*3*) of this section because the plan does provide benefits for services on an out-of-network basis if the services cannot effectively be provided in network. Accordingly, the notice of final internal adverse benefit determination is required to refer to the exception to the out-of-network exclusion and should describe the plan's standards for determining effectiveness of services, as well as how services available to the claimant within the plan's network meet the plan's standard for effectiveness of services.

(2) *External review process standards.* The Federal external review process established pursuant to this paragraph (d) is considered similar to the process set forth in the NAIC Uniform Model Act and, therefore satisfies the requirements of paragraph (d)(2)) if such process provides the following.

(i) *Request for external review.* 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. 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. For example, if the date of receipt of the notice is October 30, because there is no February 30, the request must be filed by March 1. If the last filing date would fall on a Saturday, Sunday, or Federal holiday, the last filing date is extended to the next day that is not a Saturday, Sunday, or Federal holiday.

(ii) *Preliminary review*—(A) *In general.* 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 to determine whether:

(*1*) The claimant is or was covered under the plan or coverage at the time the health care item or service was requested or, in the case of a retrospective review, was covered under the plan or coverage at the time the health care item or service was provided;

(*2*) 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 or health insurance coverage (*e.g.*, worker classification or similar determination);

(*3*) The claimant has exhausted the plan's or issuer's internal appeal process unless the claimant is not required to exhaust the internal appeals process under paragraph (b)(1) of this section; and

(*4*) The claimant has provided all the information and forms required to process an external review.

(B) Within one business day after completion of the preliminary review, the plan or issuer must issue a notification in writing to the claimant. If the request is complete but not eligible for external review, such notification must include the reasons for its ineligibility and current contact information, including the phone number, for the Employee Benefits Security Administration. If the request is not complete, such notification must describe the information or materials needed to make the request complete and the plan or issuer must allow a claimant to perfect the request for external review within the four-month filing period or within the 48 hour period following the receipt of the notification, whichever is later.

(iii) *Referral to Independent Review Organization*—(A) *In general.* The group health plan or health insurance issuer must assign an IRO that is accredited by URAC or by similar nationally-recognized accrediting organization to conduct the external review. The IRO referral process must provide for the following:

(*1*) The plan or issuer must ensure that the IRO process is not biased and ensures independence;

(*2*) The plan or issuer must contract with at least three (3) IROs for assignments under the plan or coverage and rotate claims assignments among them (or incorporate other independent, unbiased methods for selection of IROs, such as random selection); and

(*3*) The IRO may not be eligible for any financial incentives based on the likelihood that the IRO will support the denial of benefits.

(*4*) The IRO process may not impose any costs, including filing fees, on the claimant requesting the external review.

(B) *IRO contracts.* A group health plan or health insurance issuer must include the following standards in the contract between the plan or issuer and the IRO:

(*1*) The assigned IRO will utilize legal experts where appropriate to make coverage determinations under the plan or coverage.

(*2*) The assigned IRO will timely notify a claimant in writing whether the request is eligible for external review. This notice will include a statement that the claimant may submit in writing to the assigned IRO, within ten business days following the date of receipt of the notice, additional information. This additional information must be considered by the IRO when conducting the external review. The IRO is not required to, but may, accept and consider additional information submitted after ten business days.

(*3*) Within five business days after the date of assignment of the IRO, the plan or issuer must provide to the assigned IRO the documents and any information considered in making the adverse benefit determination or final internal adverse benefit determination. Failure by the plan or issuer to timely provide the documents and information must not delay the conduct of the external review. If the plan or issuer fails to timely provide the documents and information, the assigned IRO may terminate the external review and make a decision to reverse the adverse benefit determination or final internal adverse benefit determination. Within one business day after making the decision, the IRO must notify the claimant and the plan.

(*4*) Upon receipt of any information submitted by the claimant, the assigned IRO must within one business

day forward the information to the plan or issuer. Upon receipt of any such information, the plan or issuer may reconsider its adverse benefit determination or final internal adverse benefit determination that is the subject of the external review. Reconsideration by the plan or issuer must not delay the external review. The external review may be terminated as a result of the reconsideration only if the plan decides, upon completion of its reconsideration, to reverse its adverse benefit determination or final internal adverse benefit determination and provide coverage or payment. Within one business day after making such a decision, the plan must provide written notice of its decision to the claimant and the assigned IRO. The assigned IRO must terminate the external review upon receipt of the notice from the plan or issuer.

(*5*) The IRO will review all of the information and documents timely received. In reaching a decision, the assigned IRO will review the claim de novo and not be bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process applicable under paragraph (b). In addition to the documents and information provided, the assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, will consider the following in reaching a decision:

(*i*) The claimant's medical records;

(*ii*) The attending health care professional's recommendation;

(*iii*) Reports from appropriate health care professionals and other documents submitted by the plan or issuer, claimant, or the claimant's treating provider;

(*iv*) The terms of the claimant's plan or coverage to ensure that the IRO's decision is not contrary to the terms of the plan or coverage, unless the terms are inconsistent with applicable law;

(*v*) Appropriate practice guidelines, which must include applicable evidence-based standards and may include any other practice guidelines developed by the Federal government, national or professional medical societies, boards, and associations;

(*vi*) Any applicable clinical review criteria developed and used by the plan or issuer, unless the criteria are inconsistent with the terms of the plan or coverage or with applicable law; and

(*vii*) To the extent the final IRO decision maker is different from the IRO's clinical reviewer, the opinion of such clinical reviewer, after considering information described in this notice, to the extent the information or documents are available and the clinical reviewer or reviewers consider such information or documents appropriate.

(*6*) The assigned IRO must provide written notice of the final external review decision within 45 days after the IRO receives the request for the external review. The IRO must deliver the notice of the final external review decision to the claimant and the plan or issuer.

(*7*) The assigned IRO's written notice of the final external review decision must contain the following:

(*i*) A general description of the reason for the request for external review, including information sufficient to identify the claim (including the date or dates 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, the treatment code and its corresponding meaning, and the reason for the plan's or issuer's denial);

(*ii*) The date the IRO received the assignment to conduct the external review and the date of the IRO decision;

(*iii*) References to the evidence or documentation, including the specific coverage provisions and evidence-based standards, considered in reaching its decision;

(*iv*) A discussion of the principal reason or reasons for its decision, including the rationale for its decision and any evidence-based standards that were relied on in making its decision;

(*v*) A statement that the IRO's determination is binding except to the extent that other remedies may be available under State or Federal law to either the group health plan or health insurance issuer or to the claimant, or to

the extent the health plan or health insurance issuer voluntarily makes payment on the claim or otherwise provides benefits at any time, including after a final external review decision that denies the claim or otherwise fails to require such payment or benefits;

(*vi*) A statement that judicial review may be available to the claimant; and

(*vii*) Current contact information, including phone number, for any applicable office of health insurance consumer assistance or ombudsman established under PHS Act section 2793.

(*viii*) After a final external review decision, the IRO must maintain records of all claims and notices associated with the external review process for six years. An IRO must make such records available for examination by the claimant, plan, issuer, or State or Federal oversight agency upon request, except where such disclosure would violate State or Federal privacy laws.

(*iv*) *Reversal of plan's or issuer's decision.* Upon receipt of a notice of a final external review decision reversing the adverse benefit determination or final adverse benefit determination, the plan or issuer immediately must provide coverage or payment (including immediately authorizing care or immediately paying benefits) for the claim.

(3) *Expedited external review.* A group health plan or health insurance issuer must comply with the following standards with respect to an expedited external review:

(i) *Request for external review.* A group health plan or health insurance issuer must allow a claimant to make a request for an expedited external review with the plan or issuer 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 paragraph (b) of this section 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 internal 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 the facility.

(ii) *Preliminary review.* Immediately upon receipt of the request for expedited external review, the plan or issuer must determine whether the request meets the reviewability requirements set forth in paragraph (d)(2)(ii) of this section for standard external review. The plan or issuer must immediately send a notice that meets the requirements set forth in paragraph (d)(2)(ii)(B) for standard review to the claimant of its eligibility determination.

(iii) *Referral to independent review organization.* (A) Upon a determination that a request is eligible for expedited external review following the preliminary review, the plan or issuer will assign an IRO pursuant to the requirements set forth in paragraph (d)(2)(iii) of this section for standard review. The plan or issuer 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.

(B) The assigned IRO, to the extent the information or documents are available and the IRO considers them appropriate, must consider the information or documents described above under the procedures for standard review. In reaching a decision, the assigned IRO must review the claim de novo and is not bound by any decisions or conclusions reached during the plan's or issuer's internal claims and appeals process.

(iv) *Notice of final external review decision.* The plan's or issuer'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 (d)(2)(iii)(B) of this section,

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 or issuer.

(4) *Alternative, Federally-administered external review process.* Insured coverage not subject to an applicable State external review process under paragraph (c) of this section and a self-insured nonfederal governmental plan may elect to use either the Federal external review process, as set forth under paragraph (d) of this section or the Federally-administered external review process, as set forth by HHS in guidance. In such circumstances, the requirement to provide external review under this paragraph (d) is satisfied.

(e) *Form and manner of notice*—(1) *In general.* For purposes of this section, a group health plan and a health insurance issuer offering group or individual health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner if the plan or issuer meets all the requirements of paragraph (e)(2) of this section with respect to the applicable non-English languages described in paragraph (e)(3) of this section.

(2) *Requirements.* (i) The plan or issuer must provide oral language services (such as a telephone customer assistance hotline) that includes 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;

(ii) The plan or issuer must provide, upon request, a notice in any applicable non-English language; and

(iii) 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.

(3) *Applicable non-English language.* 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.

(f) *Secretarial authority.* The Secretary may determine that the external review process of a group health plan or health insurance issuer, in operation as of March 23, 2010, is considered in compliance with the applicable process established under paragraph (c) or (d) of this section if it substantially meets the requirements of paragraph (c) or (d) of this section, as applicable.

(g) *Applicability date.* The provisions of this section are applicable to group health plans and health insurance issuers for plan years (in the individual market, policy years) beginning on or after January 1, 2017. Until the applicability date for this regulation, plans and issuers are required to continue to comply with the corresponding sections of 45 CFR parts 144, 146 and 147, contained in the 45 CFR, parts 1 to 199, edition revised as of October 1, 2015.

[80 FR 72278, Nov. 18, 2015]

§ 147.138 Patient protections.

(a) *Choice of health care professional*—(1) *Designation of primary care provider*—(i) *In general.* If a group health plan, or a health insurance issuer offering group or individual health insurance coverage, requires or provides for designation by a participant, beneficiary, or enrollee of a participating primary care provider, then the plan or issuer must permit each participant, beneficiary, or enrollee to designate any participating primary care provider who is available to accept the participant, beneficiary, or enrollee. In such a case, the plan or issuer must comply with the rules of paragraph (a)(4) of this section by informing each participant (in the individual market, primary subscriber) of the terms of the plan or health insurance coverage regarding designation of a primary care provider.

(ii) *Construction.* Nothing in paragraph (a)(1)(i) of this section is to be construed to prohibit the application of reasonable and appropriate geographic