

to paragraph (a)(1) of this section for plan years (in the individual market, policy years) that begin on or after September 23, 2010, or, if later, for plan years (in the individual market, policy years) that begin on or after the date that is one year after the date the recommendation or guideline is issued.

(2) *Changes in recommendations or guidelines.* A plan or issuer is not required under this section to provide coverage for any items and services specified in any recommendation or guideline described in paragraph (a)(1) of this section after the recommendation or guideline is no longer described in paragraph (a)(1) of this section. Other requirements of Federal or State law may apply in connection with a plan or issuer ceasing to provide coverage for any such items or services, including PHS Act section 2715(d)(4), which requires a plan or issuer to give 60 days advance notice to an enrollee before any material modification will become effective.

(c) *Recommendations not current.* For purposes of paragraph (a)(1)(i) of this section, and for purposes of any other provision of law, recommendations of the United States Preventive Services Task Force regarding breast cancer screening, mammography, and prevention issued in or around November 2009 are not considered to be current.

(d) *Applicability date.* The provisions of this section apply for plan years (in the individual market, for policy years) beginning on or after September 23, 2010. See § 147.140 of this Part for determining the application of this section to grandfathered health plans (providing that these rules regarding coverage of preventive health services do not apply to grandfathered health plans).

[75 FR 41759, July 19, 2010]

§ 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 of this part. 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. Paragraph (g) of this section sets forth the applicability date for 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) or (b)(3)(ii)(F) of this section).

(vi) *Final external review decision.* A *final external review decision*, as used in paragraph (d) of this section, 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 cov-

erage 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 of this part.)

(B) *Expedited notification of benefit determinations involving urgent care.* Notwithstanding the rule of 29 CFR 2560.503–1(f)(2)(i) that provides for notification in the case of urgent care claims not later than 72 hours after the receipt of the claim, for purposes of this paragraph (b)(2), a plan and issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to a claim involving urgent care as soon as possible, taking into account the medical exigencies, but not later than 24 hours after the receipt of the claim by the plan or issuer, unless the claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the plan or health insurance coverage. The requirements of 29 CFR 2560.503–1(f)(2)(i) other than the rule for notification within 72 hours 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).

(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.

(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).

(I) The plan and issuer must ensure that any notice of adverse benefit de-

termination 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), the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) 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.

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

(4) 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.* 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), regardless of whether the plan or issuer asserts that it substantially complied with the requirements of this paragraph (b)(2) or that any error it committed was de minimis. 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.

(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 45 CFR 147.128.)

(B) *Expedited notification of benefit determinations involving urgent care.* Notwithstanding the rule of 29 CFR 2560.503-1(f)(2)(i) that provides for notification in the case of urgent care claims not later than 72 hours after the receipt of the claim, for purposes of this paragraph (b)(3), an issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to a claim involving urgent care as soon as possible, taking into account the medical exigencies, but not later than 24 hours after the receipt of the claim by the issuer, unless the claimant fails to provide sufficient information to determine whether, or to what extent, benefits are covered or payable under the health insurance coverage. The requirements of 29 CFR 2560.503-1(f)(2)(i) other than the rule for notification within 72 hours 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).

(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.

(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)(2)(ii)(E).

(I) 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 health care provider, the claim amount (if applicable), the diagnosis code and its corresponding meaning, and the treatment code and its corresponding meaning).

(2) 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.

(3) The issuer must provide a description of available internal appeals and

external review processes, including information regarding how to initiate an appeal.

(4) 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.* In the case of an issuer that fails to strictly 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), regardless of whether the issuer asserts that it substantially complied with the requirements of this paragraph (b)(3) or that any error it committed was de minimis. 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 applicable State law 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.

(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.

(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 pro-

tections 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) or (b)(3) 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, the State external review process may require a nominal filing fee from the claimant requesting an external review. 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 (in the individual market, policy 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 IRO 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 devel-

oper 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 issuer (or, if applicable, the plan), as well as the claimant except to the extent the other remedies are available under State or Federal law.

(xii) The State process must require, for standard external review, that the IRO provide written notice to the claimant and the issuer (or, if applicable, the plan) 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 existing external review processes*—(i) For plan years (in the individual market, policy years) beginning before July 1, 2011, an applicable State external review process applicable to a health insurance issuer or group health plan is considered to meet the requirements of this paragraph (c). Accordingly, for plan years (in the individual market, policy years) beginning before July 1, 2011, 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) For final internal adverse benefit determinations (or, in the case of simultaneous internal appeal and external review, adverse benefit determinations) provided after the first day of the first plan year (in the individual market, policy year) beginning on or after July 1, 2011, the Federal external review process will apply 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 as of the first day of the plan year (in the individual market, policy year).

(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.

(1) *Scope*. The Federal external review process established pursuant to this paragraph (d) applies to any adverse benefit determination or final internal adverse benefit determination as defined in paragraphs (a)(2)(i) and (a)(2)(v) of this section, except that a denial, reduction, termination or, 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 paragraph (d).

(2) *External review process standards*. The Federal external review process established pursuant to this paragraph (d) will be similar to the process set forth in the NAIC Uniform Model Act and will meet standards issued by the Secretary. These standards will comply with all of the requirements described in this paragraph (d)(2).

(i) These standards will describe how a claimant initiates an external review, procedures for preliminary reviews to determine whether a claim is eligible for external review, minimum qualifications for IROs, a process for approving IROs eligible to be assigned to conduct external reviews, a process for random assignment of external reviews to approved IROs, standards for

IRO decision-making, and rules for providing notice of a final external review decision.

(ii) These standards will provide an expedited external review process for—

(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 under paragraph (b) of this section; 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 pursuant to paragraph (d)(3) of this section 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 service for which the claimant received emergency services, but has not been discharged from a facility.

(iii) With respect to claims involving experimental or investigational treatments, these standards will also provide additional consumer protections to ensure that adequate clinical and scientific experience and protocols are taken into account as part of the external review process.

(iv) These standards will provide that an external review decision is binding on the plan or issuer, as well as the claimant, except to the extent other remedies are available under State or Federal law.

(v) These standards may establish external review reporting requirements for IROs.

(vi) These standards will establish additional notice requirements for plans and issuers regarding disclosures to participants, beneficiaries, and enrollees describing the Federal external review procedures (including the right to file a request for an external review of an adverse benefit determination or

a final internal adverse benefit determination in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to participants, beneficiaries, or enrollees.

(vii) These standards will require plans and issuers to provide information relevant to the processing of the external review, including, but not limited to, the information considered and relied on in making the adverse benefit determination or final internal adverse benefit determination.

(e) *Form and manner of notice*—(1) *Group health coverage*—(i) For purposes of this section, a group health plan and health insurance issuer offering group health insurance coverage are considered to provide relevant notices in a culturally and linguistically appropriate manner—

(A) For a plan that covers fewer than 100 participants at the beginning of a plan year, if the plan and issuer provide notices upon request in a non-English language in which 25 percent or more of all plan participants are literate only in the same non-English language; or

(B) For a plan that covers 100 or more participants at the beginning of a plan year, if the plan and issuer provides notices upon request in a non-English language in which the lesser of 500 or more participants, or 10 percent or more of all plan participants, are literate only in the same non-English language.

(ii) If an applicable threshold described in paragraph (e)(1)(i) of this section is met, the plan and issuer must also—

(A) Include a statement in the English versions of all notices, prominently displayed in the non-English language, offering the provision of such notices in the non-English language;

(B) Once a request has been made by a claimant, provide all subsequent notices to the claimant in the non-English language; and

(C) To the extent the plan or issuer maintains a customer assistance process (such as a telephone hotline) that answers questions or provides assistance with filing claims and appeals, the plan or issuer must provide such assistance in the non-English language.

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(2) *Individual health insurance coverage*—(i) For purposes of this section, a health insurance issuer offering individual health insurance coverage is considered to provide relevant notices in a culturally and linguistically appropriate manner if the issuer provides notices upon request in a non-English language in which 10 percent or more of the population residing in the claimant's county are literate only in the same non-English language, determined in guidance published by the Secretary of Health and Human Services.

(ii) If the threshold described in paragraph (e)(2)(i) of this section is met, the issuer must also—

(A) Include a statement in the English versions of all notices, prominently displayed in the non-English language, offering the provision of such notices in the non-English language;

(B) Once a request has been made by a claimant, provide all subsequent notices to the claimant in the non-English language; and

(C) To the extent the issuer maintains a customer assistance process (such as a telephone hotline) that answers questions or provides assistance with filing claims and appeals, the issuer must provide such assistance in the non-English language.

(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 apply for plan years (in the individual market, policy years) beginning on or after September 23, 2010. See §147.140 of this part for determining the application of this section to grandfathered health plans (providing that these rules regarding internal claims and appeals and external review processes do not apply to grandfathered health plans).

[75 FR 43350, July 23, 2010]

45 CFR Subtitle A (10–1–10 Edition)

§ 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) *Example.* The rules of this paragraph (a)(1) are illustrated by the following example:

Example. (i) *Facts.* A group health plan requires individuals covered under the plan to designate a primary care provider. The plan permits each individual to designate any primary care provider participating in the plan's network who is available to accept the individual as the individual's primary care provider. If an individual has not designated a primary care provider, the plan designates one until one has been designated by the individual. The plan provides a notice that satisfies the requirements of paragraph (a)(4) of this section regarding the ability to designate a primary care provider.

(ii) *Conclusion.* In this *Example*, the plan has satisfied the requirements of paragraph (a) of this section.

(2) *Designation of pediatrician as 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 the designation of a participating primary care provider for a child by a participant, beneficiary, or enrollee, the plan or issuer must permit the participant, beneficiary, or enrollee to designate a physician (allopathic or osteopathic) who specializes in pediatrics as the child's primary care provider if the provider participates in the network of the plan or issuer and is available to accept the child. In such a case, the plan or issuer