

July 28, 2010

TO: Trion

RE: PPACA Provisions on Group Health Plans and Health Insurance Issuers
Relating to Internal Claims and Appeals, and External Review Processes

On July 23, the U.S. Department of Health and Human Services, U.S. Department of Labor, and the U.S. Department of the Treasury (collectively, the “Departments”) issued interim final regulations (“IFR”) that set forth rules for internal claims and appeals and external review processes for sponsors of non-grandfathered group health plans (i.e, self-insured), and issuers offering non-grandfathered group health insurance coverage. This memorandum provides an overview of the new rules and additional details on the processes and procedures group health plans and issuers of group coverage will have to follow starting with plan years after September 23, 2010.¹

It is important to keep in mind that the IFR does not apply to grandfathered plans. It follows that to the extent a grandfathered plan is considering changes that would cause loss of grandfathered status, it should familiarize itself with these requirements to make an informed decision about the relative costs and benefits of maintaining grandfathered status versus any additional costs that would be associated with compliance with these new regulations.

Overview

Public Health Services Act (“PHSA”) Section 2719, as added by the Patient Protection and Affordable Care Act (“PPACA”), requires that group health plans and health insurance coverage implement certain internal claims and appeals and external review processes. Essentially, the IFR adds to the internal claims and appeals procedures contained in existing U.S. Department of Labor (“DOL”) regulations, with which ERISA plans are already obligated to comply, and with which many non-ERISA plans reportedly comply voluntarily. The Departments characterize these additional internal claims and appeals procedures as “clarifications” of the existing DOL regulations, and therefore, do not anticipate that the

¹ The IFR contains requirements for issuers of individual coverage; however the focus of this discussion will be the requirements applicable to group health plans and issuers of group coverage.

additional requirements will present a significant new burden. The new external review requirements, in contrast, may represent a more significant new burden because self-insured ERISA plans, and plans in states with no or limited external review requirements, would now become subject to an external review requirement.

Internal Claims and Appeals Processes

PHSA Section 2719 provides that all plans and issuers must incorporate the internal claims and appeals processes set forth in the DOL regulations that presently apply only to ERISA plans (hereafter referred to as “DOL claims procedure regulation”),² as amended by the IFR. The IFR adds the following six new requirements to those already mandated by the DOL claims procedure regulation.

First, the IFR broadens the definition of “adverse benefit determination” compared with the DOL claims procedure regulation, in that it now also includes a rescission of coverage.

Second, the IFR provides that a plan or 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 health insurance coverage, 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.

Third, the IFR provides additional criteria to ensure that a claimant receives a “full and fair” review. In addition to complying with the requirements of the DOL claims procedure regulation, the plan or issuer must provide the claimant with any new or additional evidence considered in connection with the claim. Moreover, before the plan or issuer can issue an adverse benefit determination, the claimant must be provided with the rationale for the plan’s decision.

Fourth, the IFR provides new criteria with respect to avoiding conflicts of interest. Specifically, the plan or issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. Thus, decisions regarding hiring, compensation, termination, promotion, or other similar matters with respect to any individual must not be made based upon the likelihood that the individual will support a denial of benefits.

Fifth, the IFR provides new standards regarding notice to enrollees. Specifically, a plan or issuer must provide notice to enrollees in a culturally and linguistically appropriate manner, and ensure that any notice of adverse benefit determination includes information sufficient to identify the claim involved. In some circumstances, this will require notice be provided in a non-English language as well as in English.

² Codified at 29 C.F.R. 2560.503-1. See the [Analysis](#) below for further discussion of the DOL claims procedure regulation.

Sixth, the IFR provides that, in the case of a plan or issuer that fails to strictly adhere to all of the requirements of the internal claims and appeals process, a claimant may initiate external review (such as judicial review) notwithstanding the fact that the claimant may not have exhausted the internal claims and appeals process.

In addition to these six new requirements, the statute and IFR require a plan and issuer to provide continued coverage pending the outcome of an internal appeal. Moreover, individuals in urgent care situations and individuals receiving an ongoing course of treatment may be allowed to proceed with expedited external review at the same time as the internal appeals process.

External Review Processes

With respect to external review, PHS section 2719 provides a system for applicability of either a State external review process or a Federal external review process. The IFR provides rules for determining which process applies, as well as substantive guidance regarding each process.

For issuers in states that have a mandated external review process, if that process applies to and is binding upon that issuer, and if the state process includes, at a minimum, the consumer protections presently set forth in the National Association of Insurance Commissioners (NAIC) Uniform Model Act (discussed further below), then the IFR requires the issuer to comply with the applicable State external review process and not with the Federal external review process.³ HHS will make determinations as to whether state external review laws satisfy the minimum consumer protections in the NAIC Uniform Model Act. In the meantime, the Departments will deem existing state external review processes to satisfy the IFR's requirements until July 1, 2011, and issuers who are subject to state external review processes must comply with those state requirements for plan years beginning before July 1, 2011. It is anticipated that for plan years starting after July 1, 2011, issuers will have guidance from HHS as to whether or not their state's external review process satisfies the IFR requirements, and whether the plan will need to comply instead with the federal process because their state's law fails to meet the IFR's requirements.

In any event, to the extent an employer's health benefits are provided through health insurance coverage, it will be the issuer's responsibility, and not that of the plan sponsor, to satisfy the external review obligation.

The IFR urges states to use the period between now and July 1, 2011 to ensure that their external review laws are consistent with the requirements set forth in the IFR, and expresses the Departments' preference that states take the lead in enforcing external review requirements with federal enforcement only as a backstop. The IFR also urges states with limited external review requirements (e.g., ones that apply only to HMOs) to expand their external review mandates to apply to the entire market, and warns that the Departments may step in and impose the federal

³ While state external review laws generally would not be applicable to self-insured plans, the IFR notes that there could be some exceptions, namely, non-federal governmental plans and church plans that are not subject to ERISA, and multiple-employer welfare arrangements ("MEWAs") which can be subject to both ERISA and state insurance laws. Self-insured plans in these categories should be aware that a state external review process could apply to them if the state process meets the IFR's requirements.

regime market-wide in states that fail to expand external review requirements to the entire group market.

A plan or issuer that is not subject to a state external review process (either because the plan is covered by ERISA; it is under the jurisdiction of a state that lacks an external review law; or is under the jurisdiction of a state law that does not meet the IFR's consumer protection requirements, as determined by HHS) must comply with a federal external review process which is yet to be established by HHS.

The IFR does, however, describe the scope of claims eligible for review under the federal process, as well as the standards that must apply to claimants, plans, and issuers under this process. Under the Federal external review process, the terms "adverse benefit determination" and "final internal adverse benefit determination" are defined the same as they are for purposes of internal claims and appeals (and thus include rescissions of coverage). However, an adverse benefit determination that relates to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of a group health plan (i.e., worker classification and similar issues) is not within the scope of the Federal external review process.

Once established, the Federal external review process will apply standards similar to the process set forth in the NAIC Uniform Model Act (as detailed in the Analysis below). The IFR advises that the Federal process will provide for expedited external review and additional consumer protections with respect to external review for claims involving experimental or investigational treatment. The Departments further advise that they will provide additional guidance on how non-grandfathered self-insured plans that currently maintain an internal review and appeals process that is also capable of meeting the requirements for the federal external review process can be deemed to be in compliance with the federal external review requirements, which should ease compliance burdens for these plans.

Analysis

I. Scope of and Definitions in the Interim Final Regulations (“IFR”)

A. Scope of the IFR

The IFR sets forth rules implementing PHSA section 2719 as added by the PPACA for internal claims and appeals and external review processes for non-grandfathered group health plans and health insurance coverage. Regarding internal claims and appeals processes for group health coverage, PHSA section 2719 requires plans and issuers to incorporate the processes set forth in the DOL claims procedure regulation (29 C.F.R. 2560.503-1) – with which ERISA plans are already obligated to comply, and with which many non-ERISA plans reportedly comply voluntarily – and update such processes in accordance with standards established by the Secretary of Labor. The IFR provides such updated standards for compliance. The Departments characterize these updated standards as “clarifications” of the DOL claims procedure regulation, and therefore, do not anticipate that the additional requirements will present a significant new burden. The Department of Labor is also considering further updates to its claims procedure regulation and expects to issue future regulations that will propose more comprehensive updates to the standards for plan internal claims and appeal processes.

The IFR also contains new external review requirements, which in contrast may represent a significant new burden because self-insured ERISA plans, and plans in states with no or limited external review requirements, would now become subject to an external review requirement. Further, the IFR sets forth detailed rules related to the form and manner of providing notices in connection with internal claims and appeals and external review processes.

B. Significant New Definitions in the IFR

The IFR sets forth new, generally broader definitions of terms that have previously been defined by regulation or statute.

1. Adverse Benefit Determination

An “adverse benefit determination” is defined in the IFR by incorporating the definition under the DOL claims procedure regulation, but now also includes a rescission of coverage. Thus, in addition to a rescission of coverage, an adverse benefit determination means any of the following:

A denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit, including any such denial, reduction, termination, or failure to provide or make payment that is based on a determination of a participant’s or beneficiary’s eligibility to participate in a plan, and including, with respect to group health plans, a denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item

or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate.⁴

2. Final Internal Adverse Benefit Determination

A “final adverse benefit determination” is the upholding of an adverse benefit determination at the conclusion of the internal appeals process or an adverse benefit determination with respect to which the internal appeals process has been deemed exhausted.

II. Internal Claims and Appeals Process

The IFR requires group health plans and health insurance issuers offering group or individual health insurance coverage to implement an effective internal claims and appeals process. The regulations set forth separate rules for group health coverage and individual health insurance coverage (though the scope of this memorandum is limited to rules for group health coverage).

A. DOL Claims Procedure Regulation

PHSA Section 2719 provides that all plans and issuers must incorporate the internal claims and appeals processes set forth in the DOL claims procedure regulation, codified at 29 C.F.R. 2560.503-1, which presently only applies to ERISA plans. Thus, for purposes of compliance with the IFR, a health insurance issuer offering health insurance coverage in connection with a group health plan is subject to the DOL claims procedure regulation to the same extent as if it were a group health plan.

Under the DOL claims procedure regulation, every plan must establish and follow “reasonable” claims procedures. In order to be deemed “reasonable,” a claims procedure must include:

1. The Summary Plan document has to describe all procedures for obtaining prior approval for a benefit and all related time frames.
2. The Claims Procedures cannot contain any requirement and cannot be administered in any way that unduly hampers or inhibits the initiation or processing of a claim (*e.g.*, no fees may be charged in connection with filing a claim).
3. An authorized representative of the claimant must be allowed to pursue a benefit claim or appeal with a health plan; in the case of a claim involving urgent care, a health care professional with knowledge of a claimant’s medical condition is allowed to act on the claimant’s behalf with no further authorization.
4. A plan cannot require that a claimant file more than two levels of internal appeals of an adverse benefit determination before having the option of bringing suit in federal court.

⁴ 29 C.F.R. 2560.503-1(m)(4) (DOL claims procedure regulation).

5. If the plan offers additional voluntary levels of appeal to the claimant, the Plan must make extensive information available to the claimant about the procedure; the appeal must be truly voluntary, and the claimant cannot suffer any negative consequences for not choosing to participate in it.

6. The plan's procedure may provide for arbitration of benefit disputes at one of the two levels of appeal only if the following two conditions are met: 1) the arbitration is conducted in a manner that meets the timeframe and notice requirements; 2) the arbitration is non-binding, meaning that it may not limit the claimant's ability to challenge the determination in court.

Additionally, every Plan must establish a procedure where the claimant can appeal an adverse decision and receive a full review of the claim and the adverse decision. In order to do this the Plan must do the following:

1. Provide claimants with the opportunity to submit written comments, documents, and other information relating to the claim.
2. Allow the claimant reasonable access to and copies of, upon request and free of charge, all documents, records and other relevant information related to the claim.
3. Provide a review that takes into account everything submitted by the claimant (whether submitted in the original claim or not).
4. Provide claimants at least 180 days after receipt of an adverse benefit determination to appeal.
5. Provide a review that does not give deference to the original decision and that is not conducted by either the same person who made the initial decision or by a subordinate of that individual.
6. When a decision is based on a medical judgment, the reviewer shall consult with an expert in the necessary field with appropriate training and experience and shall disclose the identity of any expert consulted by the Plan, whether that expert was relied upon or not in making the final decision.
7. For cases involving urgent care claims, the Plan must provide for an expedited review process which allows the claimant to submit the appeal either orally or in writing.

B. Additional Requirements Under IFR

The IFR sets forth six new requirements in addition to those in the DOL claims procedure regulation.

First, as indicated above, the definition of “adverse benefit determination” is broader than the definition in the DOL claims procedure regulation, in that it also includes a rescission of coverage. By referencing the DOL claims procedure regulation, an adverse benefit determination eligible for internal claims and appeals processes under the IFR includes a denial, reduction, or termination of, or a failure to provide or make a payment (in whole or in part⁵) for a benefit, including any such denial, reduction, termination, or failure to provide or make a payment that is based on:

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

A denial, reduction, or termination of, or a failure to provide or make a payment for a benefit can include both pre-service claims (*e.g.*, a claim resulting from the application of any utilization review) as well as post-service claims. An adverse benefit determination includes any rescission of coverage whether or not there is an adverse effect on any particular benefit at that time. The regulations restricting rescissions generally define a rescission as a cancellation or discontinuance of coverage that has retroactive effect, except to the extent it is attributable to a failure to timely pay required premiums or contributions toward the cost of coverage, or in the case of fraud or an intentional misrepresentation of material fact.

Second, the IFR provides that a plan or issuer must notify a claimant of a benefit determination (whether adverse or not) with respect to a “claim involving urgent care”⁶ as soon as possible, taking into account the medical exigencies, but not later than 24 hours after the

⁵ “Failure to make a payment in whole or in part” includes any instance where a plan pays less than the total amount of expenses with regard to a claim, including a denial of part of the claim due to the terms of a plan or health insurance coverage regarding copayments, deductibles, or other cost-sharing requirements. *See* the Departments of Labor’s Frequently Asked Questions (FAQs) About the Benefit Claims Procedure Regulations, FAQ C-12, at www.dol.gov/ebsa.

⁶ Under the DOL claims procedure regulation, a “claim involving urgent care” is a claim for medical care or treatment with respect to which the application of the time periods for making non-urgent care determinations could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function; or, in the opinion of a physician with knowledge of the claimant’s medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.

receipt of the claim by the plan or health insurance coverage, 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. Notably, this is a change from the requirements of the DOL claims procedure regulation, which generally requires a determination not later than 72 hours after receipt of the claim by a group health plan for urgent care claims.

Third, the IFR provides additional criteria to ensure that a claimant receives “full and fair review.” Specifically, in addition to complying with the requirements of the DOL claims procedure regulation, the plan or issuer must provide the claimant, free of charge, with any new or additional evidence considered, relied upon, or generated by 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 adverse benefit determination on review is required to be provided to give the claimant a reasonable opportunity to respond prior to that date.

Fourth, the IFR provides new criteria respecting conflicts of interest. The plan or issuer must ensure that all claims and appeals are adjudicated in a manner designed to ensure the independence and impartiality of the persons involved in making the decision. 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 a denial of benefits. For example, a plan or issuer cannot provide bonuses based on the number of denials made by the claims adjudicator.

Fifth, the IFR provides new standards regarding notice to enrollees. Specifically, a plan or issuer must provide notice to enrollees in a culturally and linguistically appropriate manner. Depending on the number of people in a plan who are literate only in the same non-English language, this might require notice be provided in a non-English language. In the group market, the threshold differs depending on the number of participants in the plan:

- For a plan that covers 100 or more participants at the beginning of a plan year, the threshold is the lesser of 500 participants or 10 percent of all plan participants being literate only in the same non-English language.
- For a plan that covers fewer than 100 participants at the beginning of a plan year, the threshold is 25 percent of all plan participants being literate only in the same non-English language.

If an applicable threshold is met, notice must be provided upon request in the non-English language. Additionally, the plan or issuer must also include a prominently displayed statement in the English version of all notices offering the provision of such notices in the non-English language; this statement must be written in the non-English language. Once a request has been made by a claimant, the plan or issuer must provide all subsequent notices to a claimant in the non-English language. On top of this, customer assistance processes (such as telephone hotlines), to the extent they are maintained, must be provided in the non-English language.

Additionally, by incorporating paragraph (g) of the DOL claims procedure regulation, the notice must be written in a manner calculated to be understood by the claimant and generally must include any specific reasons for the adverse determination, reference to the specific provision on which the determination is based, a description of any additional information required to perfect the claim, and a description of the internal appeal process.

The DOL claims procedure regulation also requires that the notice be provided in accordance with specified timeframes for urgent care claims, pre-service claims, and post-service claims. For urgent care claims, notice must be provided “as soon as possible, taking into account the medical exigencies, but not later than 72 hours” after the claimant’s request for review of an adverse benefit determination. For pre-service claims, notice must be provided “within a reasonable period of time appropriate to the medical circumstances,” not later than 30 days after receipt of the claimants request for review of an adverse benefit determination. For post-service claims, notice must be provided “within a reasonable period of time,” not later than 30 days for plans that allow one appeal of an adverse determination, and not later than 60 days for plans that allow two such appeals.

The IFR also contains additional content requirements for these notices. Any notice of an adverse benefit determination or final internal adverse benefit determination must include sufficient information to identify the claim involved. This includes the date of service, health care provider, and the claim amount (if applicable), as well as the diagnosis code, the treatment code, and the corresponding meanings of these codes. The reason(s) for the determination must include 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.

Additionally, the plan or issuer must provide a description of available internal appeals and external review processes, including information regarding how to initiate an appeal. Finally, the plan or issuer must disclose the availability of, and contact information for, any applicable office of health insurance consumer assistance or ombudsman established under PHSA section 2793 to assist enrollees with the internal claims and appeals and external review processes.⁷

Sixth, the IFR provides that, in the case of a plan or issuer that fails to strictly adhere to all the requirements of the internal claims and appeals process with respect to a claim, the claimant is deemed to have exhausted the internal claims and appeals process, even if the plan or issuer substantially complied with these requirements, or an insignificant error was committed. Accordingly, upon such a failure, the claimant may initiate an external review and pursue any available remedies under applicable law, such as judicial review.

⁷ The Departments intend to issue model notices that could be used to satisfy all the notice requirements under the IFR in the near future.

C. Continued Coverage Pending Appeal

The IFR requires a plan and issuer to provide continued coverage pending the outcome of an internal appeal. For this purpose, the plan or issuer must comply with the requirements of the DOL claims procedure regulation, which generally prohibits a plan or issuer from reducing or terminating an ongoing course of treatment without providing advance notice and an opportunity for advance review. Additionally, individuals in urgent care situations and individuals receiving an ongoing course of treatment may be allowed to proceed with expedited external review at the same time as the internal appeals process.

III. External Review

PHSA Section 2719 and the IFR provide that plans and issuers must comply with either a State external review process or a Federal external review process. The IFR provides a basis for determining whether plans and issuers must comply with an applicable State external review process or with the federal process. This determination depends upon (a) whether or not the plan is governed by ERISA;⁸ (b) whether or not a particular State has in place an external review process, and (c) the consumer protections afforded by such a process.

As a general matter, ERISA plans, including self-insured plans, will be governed by the federal external review process. As previously noted, however, the IFR explains that there could be some self-insured plans, namely non-federal governmental plans and church plans that are not subject to ERISA, as well as MEWAs that are subject to both ERISA and state insurance laws, that could be subject to the state process. Self-insured plans in these categories should accordingly be aware that a state external review process could apply to them if the state process meets the IFR's requirements.

A. State Standards for External Review

For health insurance coverage, if a State external review process that applies to and is binding on an issuer includes the consumer protections set forth in the NAIC Uniform Model Act as determined by HHS, the issuer must comply with the applicable State external review process and not with the Federal external review process. Note that to the extent that benefits under a group health plan are provided through health insurance coverage, the issuer is required to satisfy the obligation to provide an external review process, so the plan itself is not required to comply with either the External review process or the Federal external review process.

⁸ As previously noted, while state external review laws generally would not be applicable to self-insured plans, the IFR explains that there could be some exceptions, namely, non-federal governmental plans and church plans that are not subject to ERISA, and MEWAs that are subject to both ERISA and state insurance laws. Self-insured plans in these categories should accordingly be aware that a state external review process could apply to them if the state process meets the IFR's requirements.

The elements from the NAIC Model Act that must be included for a State external review process to apply are briefly described in the Appendix to this Memorandum, and include, for example, procedural and notice requirements for external review of adverse benefit determinations (and final internal adverse benefit determinations) that are based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.

In the future, HHS will make affirmative determinations as to whether States' external review processes meet these requirements (and thus whether issuers and plans subject to States' external review processes must comply with the State review process rather than the Federal external review process). In the meantime, a transition period will be provided, during which existing State external review processes will be treated as satisfying these requirements. Thus, for plan or policy years beginning before July 1, 2011, a health insurance issuer subject to an existing State external review process must comply with that State external review process and not the Federal external review process.

The IFR urges states to use the transition period to ensure that their external review laws are consistent with the requirements set forth in the IFR, and expresses the Departments' preference that states take the lead in enforcing external review requirements with federal enforcement only as a backstop.

Additionally, the Departments advise that they will provide further guidance on how non-grandfathered self-insured plans that currently maintain an internal review and appeals process that is also capable of meeting the requirements for the federal external review process can be deemed to be in compliance with the federal external review requirements, thereby easing the compliance burden for these plans.

1. Timing

The applicable external review process for any particular claim is based on the external review process applicable to the plan or issuer at the time a final internal adverse benefit determination is provided. For this purpose, the final internal adverse benefit determination includes a deemed-final adverse benefit determination in which the internal claims and appeals process is exhausted because of the failure by the plan or issuer to comply with the requirements of the internal claims and appeals process. Thus, where a State's external review process fails to meet the minimum standards, external review of final internal adverse benefit determinations provided prior to January 1, 2012 (the first day of the first calendar year on or after July 1, 2011, the end of the transition period) must comply with the State external review process. Conversely, external reviews of final internal adverse benefit determinations provided on or after January 1, 2012 must meet the alternative Federal external review requirements.

2. Scope of State External Review Processes

The IFR did not set a specific standard for availability of State external review processes that are considered sufficient to meet the minimum consumer protections of the NAIC Uniform Model Act. (Some States' current processes do not apply to all issuers in the State.) If it is determined under future regulations that it market-wide availability of the State external review

process is required, plans and issuers would be subject to the Federal external review process in States that do not apply the State external review process to all issuers in the State. Alternatively, if it is determined that universal availability is not required, those plans and issuers that are not subject to the State external review process would be subject to a Federal external review process.

B. Federal External Review Process

A plan or issuer that is not subject to an applicable State external review process, either because the plan is governed by ERISA, the State does not have such a process in place, or because the state's process does not meet the IFR's minimum standards, must comply with the rules for a Federal external review process. Note, however, that the Departments have not yet promulgated the specific rules governing the Federal external review process. Thus far, the IFR only sets forth the scope of claims eligible for review under this process, and the standards that would apply to claimants, plans, and issuers under this process.

More specifically, under the Federal external review process, the terms "adverse benefit determination" and "final internal adverse benefit determination" are defined the same as they are for purposes of internal claims and appeals (and thus include rescissions of coverage). However, an adverse benefit determination that relates to a participant's or beneficiary's failure to meet the requirements for eligibility under the terms of a group health plan (*i.e.*, worker classification and similar issues) is not within the scope of the Federal external review process.

The IFR advises that the Federal external review process will be similar to the State external review processes that comply with the minimum standards delineated in the IFR. Additionally, the Federal review process, like the State external review process, must provide for expedited external review and additional consumer protections with respect to external review for claims involving experimental or investigational treatment.

IV. Comment Period

It should be kept in mind that the Departments seek public comment on all aspects of the IFR. To the extent that clients view the rules as particularly uninformed or problematic, there is an opportunity to offer such views to the agencies. Comments on the IFR will be due 60 days after the date the IFR is published in the Federal Register, that is, on or about September 21, 2010.

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APPENDIX

Minimum consumer protections that must be included in State external review processes in order to avoid Federal process applicability.

The State process must:

- Provide for the external review of adverse benefit determinations (and final internal adverse benefit determinations) that are based on medical necessity, appropriateness, health care setting, level of care, or effectiveness of a covered benefit.
- Require issuers to provide effective written notice to claimants of their rights in connection with an external review for an adverse benefit determination.
- To the extent the State process requires exhaustion of an internal claims and appeals process, make exhaustion unnecessary if (a) the issuer has waived the exhaustion requirement, (b) the claimant has exhausted (or is considered to have exhausted) the internal claims and appeals process under applicable law; or (c) the claimant has applied for expedited external review at the same time as applying for an expedited internal appeal.
- Provide that the issuer against which a request for external review is filed must pay the cost of an independent review organization (IRO) for conducting the external review. If the State pays this cost, this obligation is met. The State process may require a filing fee from the claimant requesting an external review so long as it does not exceed \$25, is refunded to the claimant if the adverse benefit determination is reversed through external review, and is waived if payment of the fee imposes an undue financial hardship. The annual limit on filing fees for any claimant within a single year must not exceed \$75.
- Not impose a restriction on the minimum dollar amount of a claim for it to be eligible for external review.
- Allow at least four months after the receipt of a notice of an adverse benefit determination or final internal adverse benefit determination for a request for an external review to be filed.
- Provide that an IRO will be assigned on a random basis or another method of assignment that assures the independence and impartiality of the assignment process by a State or independent entity, and in no event is selected by the issuer, plan, or individual.
- Provide for maintenance of a list of approved, accredited IROs qualified to conduct the review based on the nature of the health care service that is the subject of the review.
- Provide that any approved IRO has no conflicts of interest that will influence its independence.
- Allow the claimant to submit to the IRO in writing additional information that the IRO must consider when conducting the external review and require that the claimant is notified of such right to do so. The process must also require that any additional information submitted by the claimant to the IRO must be forwarded to the issuer within one business day of receipt by the IRO.

- Provide that the decision is binding on the plan or issuer, as well as the claimant, except to the extent that other remedies are available under State or Federal law.
- Provide that the IRO must generally provide written notice to the issuer and the claimant of its decision to uphold or reverse the adverse benefit determination.
- Provide for an expedited external review in certain circumstances and, in such cases, the State process must provide notice of the decision as expeditiously as possible, but not later than 72 hours after the receipt of the request.
- Require that issuers include a description of the external review process in the summary plan description, policy, certificate, membership booklet, outline of coverage, or other evidence of coverage it provides to claimants.
- Require that IROs maintain written records and make them available upon request to the State
- Follow procedures for external review of adverse benefit determinations involving experimental or investigational treatment.