September 2010

Federal External Review Procedures – New Regulations Issued

Standardization of how medical claims are handled is one of the primary goals of the Patient Protection and Affordability Act (PPACA). PPACA mandates one set of Federal rules for handling both initial claims and internal claim appeals for all group health plans (GHPs), whether insured or self-insured, and for all individual health insurance. The only exception being "grandfathered" GHPs and insurance policies so long as they maintain their grandfathered status. (See our article "Interim Final Rules Relating to Internal Claims and Appeals and External Review Process").

For external reviews of denied claims, PPACA has mandated not one but two sets of rules. The first is based on State External Review Laws found in virtually every State's insurance code. As also explained in our previous article, the State External Review Laws will apply to health insurers and virtually all GHPs except for self-funded GHPs that are subject to ERISA. Starting July 1, 2011, however, those State External Review Laws will be replaced by the second set of rules, the Federal External Review Procedures, unless the U.S. Department of Health and Human Services (HHS) finds that those laws meet minimum standards established by the National Association of Insurance Commissioners (NAIC).

PPACA instructed HHS to issue the requirements for the Federal External Review Procedure, which was done August 23, 2010. The new Federal External Review Procedure rules are effective with the first plan year beginning on or after September 23, 2010 except they will not apply to "grandfathered" GHPs and insurance policies so long as they maintain their grandfathered status.

Application of the Federal Standards and Procedures

The new Federal External Review Procedures apply to all non-grandfathered-

- Self-funded GHPs that are subject to ERISA;
- Self-funded GHPs that are not subject to ERISA, such as non-federal governmental and church plans, unless a State External Review Laws is made applicable to such plans;
- Group and individual health insurance policies in States that do not have an applicable a State External Review Law; and
- Starting July 1, 2011, group and individual health insurance policies in States that do not have a State External Review Law that meets the NAIC minimum standards, as determined by HHS.

They will not apply to plans that qualify as HIPAA "excepted" benefits such as separate dental and vision plans and most Flexible Spending Accounts.

There is one other possible exception provided in DOL Technical Release 2010-01 but it is unlikely to be used very often. If a State enacts a State External Review Law that applies to self-funded GHPs subject to ERISA, such GHPs may chose to voluntarily comply with that State Law rather than follow the Federal Procedures. Voluntary compliance with state standards will only be feasible if States choose to expand the existing processes to plans that are not currently subject to the state laws -- such as self-funded ERISA plans. Otherwise, those plans must use the federal process.

> *Comment: It is doubtful that many States will choose to enact or expand processes to plans that are not currently subject to State laws such as self-funded ERISA plans. In fact, many States may find it difficult to pass State External Review Laws for insurers that are acceptable to HHS.*
>
> *Comment: Voluntary compliance with State processes may be difficult or not practical for self-funded group health plans if the employer has employees in more than one State.*

Responsibility for Compliance

Where a GHP is funded with an insurance policy, the carrier, not the employer sponsoring the plan, is responsible for complying under an insured plan. The plan sponsor of a GHP subject to the Federal Procedures is responsible for complying under a self-funded plan - including plans where an insurance carrier administers claims.

Federal External Review Standards and Procedures

Technical Release 2010-01 includes minimum review standards, specific processes and specific time frames that must be followed. This release contains:

- Rules for selecting and contracting with an outside entity to conduct external reviews;
- A description of a four-step process, including maximum time frames for the external appeals process;
- Additional requirements for an expedited review for urgent claims; and
- Three model notices to be used to communicate claim and review determinations.

The guidance provided is a "safe harbor", protecting a GHP against enforcement action by the IRS or the Department of Labor, rather than a set of specific minimum requirements that each GHP must follow. The purpose is to provide GHPs with a means to ensure an unbiased, outside review of claim decisions. The process described is not the only method of complying with the Federal External Review requirements. However, GHPs that decide to implement procedures that are materially different from the safe harbor should proceed very cautiously.

Independent Review Organizations

One of the key requirements under the new Federal Standards is the requirement that the GHP provide for a claim review conducted by an outside entity – an Independent Review Organization (IRO). This is a new requirement for many GHPs, particularly self-funded ERISA plans that have not been subject to any state external review process. It may also be new for some self-funded non-ERISA plans.

The IROs used for external reviews must be accredited by a nationally recognized organization such as URAC (URAC is cited as an example in the guidance). The IRO selected for each external claim review

must be selected using a method intended to ensure an independent, unbiased IRO. The Technical Release identifies random selection from among a minimum of three IROs as one method to help assure independence.

In addition to national accreditation and a selection method designed to ensure an unbiased review, the contract between each IRO and the GHP must include a specified list of provisions, which contain minimum procedures and time frames to be used for external reviews.

> *Comment: the safe harbor provided in the DOL's Technical Release states the GHP must contract with at least three IROs. Based on comments made by agency representatives during the DOL's September 9 webcast, the contract may be between the IRO and the GHP's TPA. However, while the GHP may not be required to have its own contract with the IROs, the GHP still has the responsibility to ensure that the IRO contract has the required provisions and that the TPA and IRO adhere to those requirements.*

Four Step Review Process

DOL Technical Release 2010-01 describes a detailed four-step procedure to be followed for all external reviews. Briefly, those four steps along with the required time frames (where provided) are:

1. ***Request for external review*** – the claimant must file a written (includes electronic) request for an external review with the GHP. The request must be filed no later than four months after the date the claimant receives from the GHP a notice of adverse benefit determination or final notice of adverse benefit determination.

2. ***Preliminary review and referral to an IRO*** – the GHP has five business days after receipt to complete a preliminary review of the request for external review. The purpose of the preliminary review is to confirm:

    a. The Claimant was covered under the GHP when the medical care was received;

    b. The adverse benefit determination is not related to the claimant's eligibility for coverage;

    c. The claimant has exhausted the GHP's internal appeal process (if required); and

    d. All of the information and forms required to process an external review have been provided.

    *decisions on questions relating to eligibility – such as whether or not an employee is full-time – are subject to the internal review rules, but are not eligible for external review

    The GHP must notify the claimant in writing within one business day after it completes the preliminary review. If the claim is not eligible for external review, the notice must include the reasons for ineligibility and information on how to contact the Department of Labor. If the claim is eligible for external review, but not complete, the notice must describe the information or materials needed to complete the request. The claimant must be given at least 48 hours after receipt of the notice to provide the missing information or materials (or until the end of the four-month filing time limit if later).

    Once the GHP determines that the claim is eligible for external review, it must assign an IRO to conduct the external review. The IRO selected for the review must be determined using a method

intended to prevent bias and ensure independence. The safe harbor rule suggests rotating assignments among a minimum of three nationally accredited IROs as one method.

Comment: it is not clear what happens if a GHP determines that a claim is not eligible for external review but the claimant disagrees. Presumably, the Department of labor will establish some expedited review process.

3. ***Referral to and review by an IRO*** – within five business days after the plan has assigned an IRO, the GHP must provide the IRO with any documents and information it considered in making the adverse benefit determination. A GHP's failure to provide this information when required does not extend the time frame for the process. In addition, if the plan does not provide information and documents as required, the IRO is permitted to terminate the external review and make a decision to reverse the plan's decision. If the IRO terminates the review, it must notify the claimant and the GHP within one business day.

   If the claimant sends any information directly to the IRO, the IRO must forward a copy of that information to the GHP within one business day. The GHP then has an opportunity to reconsider its decision based on the new information. Similar to the receipt of information from the GHP, this additional step does not extend or delay the review process. In other words, the clock is still ticking while additional information is received, forwarded or considered.

   If the GHP decides to reverse its previous decision and pay the claim based on the new information, it must notify the IRO and the claimant in writing within one business day. The IRO must terminate its review upon receipt of this notice.

   If no new information is received, the IRO will proceed with the external review that must be a "de novo" review – i.e., one that does not give deference to the GHP's decision. Where the information is available and appropriate, the IRO will consider the following in reaching a decision:

   - The claimant's medical records;
   - The attending health care professional's recommendation
   - Reports from other health care professionals;
   - Other documents submitted by the plan, claimant or claimant's treating provider;
   - The terms of the GHP (to ensure that the IRO's decision is not contrary to the GHP's terms);
   - Practice guidelines including evidence based standards and others developed by the Federal government or professional medical societies, boards or associations;
   - Clinical review criteria developed and used by the GHP; and
   - The opinion of the IRO's clinical reviewer(s);

4. ***IRO Decision*** -- the IRO must provide written notice of its external review decision with 45 days after it receives the request for the external review. The notice must be provided to both the claimant and the GHP and must include:

    - A general description of the reason for the request for the review with enough information to identify the claim -- e.g., the date(s) of service, name of the health care provider, the claim amount, diagnosis code (including the meaning of the code), and the general reason for the GHP's adverse benefit determination;
    - The date the IRO received the request for external review;
    - The date of the IRO's decision;
    - References to the evidence or documentation it considered in making its decision;
    - The principal reason(s) for its decision, including the rationale and any evidence-based standards used;
    - A statement that the determination is binding (except where the GHP or claimant have other legal remedies available);
    - A statement that judicial review may be available to the claimant; and
    - Current contact information (including phone number) for any available office of health insurance consumer assistance or ombudsman.

    Comment: it is again unclear whether the last item dealing with State appointed ombudsmen, is applicable to self-insured GHPs subject to ERISA, which are generally exempt from State law and State officials. Hopefully this will be clarified in the near future.

The IRO's decision is generally binding. The claimant may still have the right to pursue a judicial review (e.g., sue the GHP). The GHP may also have the right to pursue a judicial review, but may not deny or delay payment pending judicial review.

The IRO must keep appropriate records of the review materials and its decision for six years (this is one of the provisions that must be in the IRO's contract with the GHP).

Expedited Review for Urgent Care Claims

Expedited reviews are required for urgent care claims. In general, the same four-step process applies, but the time frames are considerably shorter. The GHP must permit the claimant to request an expedited external review when the claimant receives:

- An adverse benefit determination if it involves a medical condition for which the time frame for completion of an expedited internal appeal would seriously jeopardize the claimant's life, health or the ability to regain maximum function and the claimant has requested an expedited internal appeal; or
- A final internal adverse benefit determination if: **(1)** it involves a medical condition for which the time frame for completion of a standard external review would jeopardize the claimant's life, health or ability to regain maximum function, or **(2)** 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.

The GHP must conduct a preliminary review to determine that the claim is eligible for external review (step two above) and immediately send notice to the claimant. The plan must assign the IRO and transmit the required information to the IRO electronically, by phone, by fax or other available expeditious method. The IRO must follow the standard review process (step three above) including the "de novo" requirement. The IRO must provide notice of its decision as expeditiously as the claimant's medical condition requires. In all cases, the decision must be made no more than 72 hours after the IRO receives the request for an expedited external review. Because of the shortened time frames, the IRO may provide notice of its decision orally (e.g., via phone), but must then also provide written confirmation of the oral notice with 48 hours.

Comment: "Immediately" is not defined in the guidance and was not addressed in the September 9 webcast. Unless and until further guidance is provided it would seem prudent to make the determination in 24 hours or less.

Three Model Notices

Three model notices have been provided for use by GHPs and carriers: **(1)** Model Notice of Adverse Benefit Determination; **(2)** Model Notice of Final Internal Adverse Benefit Determination; and **(3)** Model Notice of Final External Review Decision. The claims administrator (carrier, TPA or GHP) would use the first two notices. The third is for use by the IRO. These notices are included as Attachment 1.

Comment: the use of these model notices may help to standardize EOBs used by carriers, TPAs and GHPs. It may also expand the amount of information provided to the claimant. For example, the EOB will need to include more information about a treatment or procedure than the five-digit CPT code.

Action Steps

The action steps for a non-grandfathered GHP depend on whether the GHP is insured or self-funded. Action steps are listed separately for each group below. GHPs that are not insured, *even if the GHP uses an insurance carrier as the claims administrator*, must comply with the rules for self-funded plans.

Insured Group Health Plans

The insurance carrier is responsible for compliance with either the State or Federal External Review Procedures by an insured GHP. The carrier must determine whether Federal or State external procedures apply and handle IRO selection, coordination and contracting. The carrier must also provide appropriate insurance contract and certificate language describing the external review process.

The plan sponsor will be responsible for updating and distributing plan materials such as SPDs. In addition, the plan sponsor may also want to review its role in the claims process. Given the additional requirements and shortened time frames, it may be more difficult for employers to provide personalized assistance during the claim appeal process. HR departments may decide to focus their efforts on providing more detailed communications about benefits and the claim process and responding to requests for information.

Self-Funded Group Health Plans

Self-funded non-grandfathered GHPs will have considerably more activities to complete. These GHPs should begin immediately to determine how they will come into compliance. These GHPs will need to coordinate with the third party administrator to determine and/or modify their respective roles and responsibilities including:

- Designation of the claim fiduciary;
- Selection and contracting with IROs;
- Responsibility for the preliminary review to determine if a claim is eligible for external review;
- Assignment of and coordination with the IRO assigned to review the claim;
- Development of appropriate language for plan communications such as SPDs;
- Updating the plan document; and
- Making needed changes to current notices such as EOBs.

Self-funded GHPs may also want to review and in some cases modify their role in the claim and appeals process. Like insured GHPs, it may be more difficult for the HR department to continue to take a "hands-on" approach. They may want to focus more on communications and responding to information requests with less involvement in the actual claim process.

> *Comment: during the September 9, agency representatives stated that the IRO contract did not have to be direct with the group health plan. These contracts could be between the TPA and the IRO with the caveat that the plan is still the party responsible for compliance. This would seem to be a viable approach where the TPA is an insurance carrier since the carrier will have IRO contracts for its insured business. It may also be viable where the TPA is the claim fiduciary, but may not be feasible where the plan has retained the claim fiduciary status. In view of the heightened scrutiny, increased requirements and shortened time frames group health plans that chose to retain the role of claim fiduciary may wish to revisit that decision.*

To date the three regulatory agencies have issued two sets of guidance on the claim and review (appeal) process. The first set issued on July 23 covered internal claim appeals; this most recent set issued one-month later covers external appeals. As with other recently issued guidance, there are open questions and we anticipate additional guidance in the future. Gallagher Benefit Services will continue to monitor developments and provide updated information as it becomes available.

GBS is committed to helping you effectively navigate this significant change for the benefit of your organization, your employees and their families. There is more to come and we look forward to assisting you. Please contact your Gallagher Representative with any questions.

Attachment 1

Model Notice of Adverse Benefit Determination

Date of Notice:
Name of Plan **Telephone/Fax**
Address **Website/Email Address**

This document contains important information that you should retain for your records.
This document serves as notice of an adverse benefit determination. We have declined to provide benefits, in whole or in part, for the requested treatment or service described below. If you think this determination was made in error, you have the right to appeal (see the back of this page for information about your appeal rights).

Case Details:

Name:	**ID Number:**
Claim #:	**Date of Service:**
Provider:	

Reason for Denial (in whole or in part):

Amt. Charged	Allowed Amt.	Other Insurance	Deductible	Co-pay	Coinsurance	Other Amts. Not Covered	Amt. Paid

YTD Credit toward Deductible:	**YTD Credit toward Out-of-Pocket Maximum:**
Diagnosis:	
Diagnostic Codes:	**Requested Service(s)/ Treatment Code:**
Treatment Category (Subcategory):	**Denial Codes:**

[If denial is not related to a specific claim, only name and ID number need to be included in the box. The reason for the denial would need to be clear in the narrative below.]

Explanation of Basis for Determination:

If the claim is denied (in whole or in part) and there is more explanation for the basis of the denial, such as the definition of a plan or policy term, include that information here.

Attachment 1

Model Notice of Adverse Benefit Determination

Important Information about Your Appeal Rights

What if I need help understanding this denial? Contact us at [insert contact information] if you need assistance understanding this notice or our decision to deny you a service or coverage.

What if I don't agree with this decision? You have a right to appeal any decision not to provide you or pay for an item or service (in whole or in part).

How do I file an appeal? Detach and send in the bottom of this form within [insert timeframe, for example, X days from the date of this notice]. [If electronic notice, insert alternate submission instructions.]

What if my situation is urgent? If your situation meets the definition of urgent under the law, your review will be conducted within 24 hours. Generally, an urgent situation is one in which your health may be in serious jeopardy or, in the opinion of your physician, you may experience pain that cannot be adequately controlled while you wait for a decision on your appeal. If you believe your situation is urgent, you may request an expedited appeal by [insert instructions for filing internal appeals (and, if applicable, simultaneous external review)].

Who may file an appeal? You or someone you name to act for you (your authorized representative) may file an appeal. [Insert information on how to designate an authorized representative.]

Can I provide additional information about my claim? Yes, you may supply additional information. [Insert any applicable procedures for submission of additional information.]

Can I request copies of information relevant to my claim? Yes, you may request copies (free of charge) by contacting us at [insert contact information].

What happens next? If you appeal, we will review our decision and provide you with a written determination. If we continue to deny the payment, coverage, or service requested or you do not receive a timely decision, you may be able to request an external review of your claim by an independent third party, who will review the denial and issue a final decision.

Other resources to help you: For questions about your appeal rights, this notice, or for assistance, you can contact the Employee Benefits Security Administration at 1-866-444-EBSA (3272). [Insert, if applicable in your state: Additionally, a consumer assistance program may be able to assist you at [insert contact information].]

Appeal Filing Form

[Insert Name and ID Number] [Insert Claim #]
[Insert Patient Name]

Detach this form and send to: [Insert name and contact information]

NAME OF PERSON FILING APPEAL: _____

☐Covered person ☐ Patient ☐ Authorized Representative

Attachment 1

Model Notice of Final Internal Adverse Benefit Determination

Date of Notice
Name of Plan **Telephone/Fax**
Address **Website/Email Address**

This document contains important information that you should retain for your records.
This document serves as notice of a final internal adverse benefit determination. We have declined to provide benefits, in whole or in part, for the requested treatment or service described below. If you think this determination was made in error, you may have the right to appeal (see the back of this page for information about your appeal rights).

Case Details:

Name:	**ID Number:**
Claim #:	**Date of Service:**
Provider:	

Reason for Denial (in whole or in part):

Amt. Charged	**Allowed Amt.**	**Other Insurance**	**Deductible**	**Co-pay**	**Coinsurance**	**Other Amts. Not Covered**	**Amt. Paid**

YTD Credit toward Deductible:	**YTD Credit toward Out-of-Pocket Maximum:**
Diagnosis:	
Diagnostic Codes:	**Requested Service(s)/ Treatment Code:**
Treatment Category (Subcategory):	**Denial Codes:**

[If denial is not related to a specific claim, only name and ID number need to be included in the box. The reason for the denial would need to be clear in the narrative below.]

Background Information: *Describe facts of the case including type of appeal and date appeal filed.*

Final Internal Adverse Benefit Determination: *State that adverse benefit determination has been upheld. List all documents and statements that were reviewed to make this final internal adverse benefit determination.*

Findings: *Discuss the reason or reasons for the final internal adverse benefit determination.*

OMB Control Number 1210-0144 (expires 01/31/2011)

Model Notice of Final Internal Adverse Benefit Determination

Important Information about Your Rights to External Review

What if I need help understanding this denial? Contact us [insert contact information] if you need assistance understanding this notice or our decision to deny you a service or coverage.

What if I don't agree with this decision? For most types of claims, you are entitled to request an independent, external review of our decision. Contact us [insert contact information] with any questions on your rights to external review.

How do I file a request for external review? [Insert instructions in place of detachable form at the bottom of this page. If there are no current procedures applicable, insert: Detach and send in the bottom of this form within [insert timeframe].]

What if my situation is urgent? If your situation meets the definition of urgent under the law, the external review of your claim will be conducted as expeditiously as possible. Generally, an urgent situation is one in which your health may be in serious jeopardy or, in the opinion of your physician, you may experience pain that cannot be adequately controlled while you wait for a decision on the external review of your claim. If you believe your situation is urgent, you may request an expedited external review by [insert instructions to begin the process (such as by phone, fax, electronic submission, etc.)].

Who may file a request for external review? You or someone you name to act for you (your authorized representative) may file a request for external review. [Insert information on how to designate an authorized representative.]

Can I provide additional information about my claim? Yes, once your external review is initiated, you will receive instructions on how to supply additional information.

Can I request copies of information relevant to my claim? Yes, you may request copies (free of charge) by contacting us at [insert contact information].

What happens next? If you request an external review, an independent organization will review our decision and provide you with a written determination. If this organization decides to overturn our decision, we will provide coverage or payment for your health care item or service.

Other resources to help you: For questions about your rights, this notice, or for assistance, you can contact the Employee Benefits Security Administration at 1-866-444-EBSA (3272). [Insert, if applicable in your state: Additionally, a consumer assistance program may be able to assist you at [insert contact information].]

Appeal Filing Form

[Insert Insurer Name] [Insert Name and ID Number]
[Insert Phone Number/ Mailing Address] [Insert Claim #]

Detach this form and send to: [Insert name and contact information]

NAME OF PERSON FILING APPEAL: _____
☐Covered person ☐ Patient ☐ Authorized Representative

OMB Control Number 1210-0144 (expires 01/31/2011)

Attachment 1

Model Notice of Final External Review Decision

Date of Notice
Name of Plan **Telephone/Fax**
Address **Website/Email Address**

This document contains important information that you should retain for your records.

This document serves as notice of a final external review decision. We have **[upheld/overturned/modified]** the denial of your request for the provision of, or payment for, a health care service or course of treatment.

Historical Case Details:

Name:	**ID Number:**
Claim #:	**Date of Service:**
Provider:	

Reason for Denial (in whole or in part):

Amt. Charged	**Allowed Amt.**	**Other Insurance**	**Deductible**	**Co-pay**	**Coinsurance**	**Other Amts. Not Covered**	**Amt. Paid**

YTD Credit toward Deductible:	**YTD Credit toward Out-of-Pocket Maximum:**
Diagnosis:	
Diagnostic Codes:	**Requested Service(s)/ Treatment Code:**
Treatment Category (Subcategory):	**Denial Codes:**

[If denial is not related to a specific claim, only name and ID number need to be included in the box. The reason for the denial would need to be clear in the narrative below.]

Background Information: *Describe facts of the case including type of appeal, date appeal filed, date appeal was received by IRO and date IRO decision was made.*

Final External Review Decision: *State decision. List all documents and statements that were reviewed to make this final external review decision.*

Findings: *Discuss the principal reason or reasons for IRO decision, including the rationale and any evidence-based standards or coverage provisions that were relied on in making this decision.*

OMB Control Number 1210-0144 (expires 01/31/2011)

Model Notice of Final External Review Decision

Important Information about Your Appeal Rights

What if I need help understanding this decision?
Contact us [insert IRO contact information] if you need assistance understanding this notice.

What happens now? If we have overturned the denial, your plan or health insurance issuer will now provide service or payment.

If we have upheld the denial, there is no further review available under the appeals process. However, you may have other remedies available under State or Federal law, such as filing a lawsuit.

Other resources to help you: For questions about your appeal rights, this notice, or for assistance, you can contact the Employee Benefits Security Administration at 1-866-444-EBSA (3272). [Insert, if applicable in your state: Additionally, a consumer assistance program may be able to assist you at [insert contact information].]