Instructions

For Making

Inherent Reasonableness Determinations

Under

Section 1842(b)(8) and 42 CFR 405.502(g) and (h)

For CMS and Contractors

Prepared

March 22, 2004
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Contract: 500-96-0026, Task 20

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Preface

This document is submitted to fulfill subtask 2.4 in Task 20 of Contract 500-96-0026, to develop and provide a manual that contains standard analyses and documentation. We found it more feasible to present two manuals.

- One manual of procedure to define CMS processes for CMS activity with respect to Inherent Reasonableness (IR) determinations, including Central Office responsibilities and related start up activities; and

- Another manual section to be placed in the IOM to provide instructions for carriers and DMERCS. Sometimes the first manual will refer to instructions in the second, to avoid duplication and to avoid maintaining identical material in two places.

The IOM manual section follows the first manual in the binder. They are on separate files on the companion disk. File "REVclm104c23s90.doc" is the IOM file. File "IR_CO_manual_mar22-04.doc" is the file for the central office procedures manual.

Note that there is a placeholder for IR Determinations in §90 of Chapter 23, "Fee Schedule Administration and Coding Requirements," in the Medicare Claims Processing Manual. So we numbered the draft accordingly. There may be other IR material in the Claims Manual chapters on drugs, ambulance, lab, and DMEPOS that should be deleted and/or cross-referred. We have not done that. We recommend that a cross-reference and hyperlink be included from each chapter to the new §90 of Chapter 23 (all in the Claims Processing Manual).

1 - Background

Title XVIII of the Social Security Act (the Act) contains various methodologies for making payment for Medicare Part B services. Section 1842(b)8 provides that payment amounts under all Part B methodologies other than physician's service under §1848 may be adjusted if the payment amount calculated by the prescribed method results in an amount that, because of its being grossly excessive or grossly deficient, is not inherently reasonable. The adjustment may be up for grossly deficient payment amount or down for grossly excessive payment amounts. The new limit may be either a specific dollar amount or may be based on a special method to be used in determining the payment amount.

Regulations at 42 CFR 405.502(g) which implement this provide that the payment amount for an item of service is considered grossly excessive or grossly deficient only if the adjustment reflected by an inherent reasonableness determination is more than 15% higher or lower than the normal price determined by Medicare program procedures. CMS has decided that adjustments of less than 15% will not be made.

Any change in the payment limit requires publishing a notice. A change based on an inherent reasonableness (IR) determination by CMS requires publishing proposed and final notices in the *Federal Register*. A contractor IR determination requires the contractor to inform the affected suppliers and Medicaid agencies of the proposed amounts and the related rationale; and also to solicit comments. In effect, a process similar to the federal process is required at the carrier/DMERC level, but Federal publication is not mandated.

Where the adjustment is more than 15% within any year, §1842(b)(9) and 42 CFR.502(h) require specified coordination with the industry and consideration of the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

Also the proposed notice must contain additional detail beyond that required where the amount of adjustment per year is less than 15%.

Note that CMS could determine a change of more than 15% is justified and elect to phase it in over two years at 15% per year or less, which would avoid the additional administrative requirements that are necessary for changes of more than 15% within a year.

This instruction provides guidelines for application of the process for making and implementing inherent reasonableness determinations

2 - Applicability

These provisions apply to Part B payments by carriers, including DMERCs, and intermediaries except the following types of payments are excluded:

- Physicians services paid under §1848;
- Part B payments made under OPPS or home health PPS;
- ESRD payments to facilities under the composite rate method 1;
- Payment made at reasonable cost.

In general it is expected that the principal services to which this applies will be DMEPOS, laboratory, ambulance, and drugs.

3 - Who May Make Inherent Reasonableness (IR) Determinations

IR determinations can be made by any of:

- CMS; or
- A carrier (including a DMERC).

In administration of the current IR process all intermediaries have reported that if they see a need for an IR determination they request the carrier or DMERC (for DMEPOS) to do it. This process will be continued. IR would seldom apply to intermediary claims but could apply for Part B services paid to facilities under a fee schedule, where the service does not meet the reasons for exclusion shown in §2.

4 - Preparing for CMS IR Determinations

CMS planning should encompass the following:

- Planning to establish staff to perform IR determinations and to monitor IR determinations by others;
- Development of resources for information;
- Planning for preparation of the Federal Register notices that are required;
- Planning for publication of IR determinations on the CMS Web site;
- Deciding how to use the PSC contractors in the process; and
- Preparation and release of IOM instruction to the contractors, providers, and suppliers.

These are discussed in the following sections.
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4.1 - Establishing Staff to Perform IR Determinations and Monitor the Process

4.1.1 - Carrier/DMERC Processes

Making IR determinations is now part of the carrier and DMERC workload. The differences in the workload composition are primarily:

- Where surveys are necessary the process is to be more structured and uniform, and
- While carriers have always notified "providers" of changes in payment amount resulting from IR determinations, the notification process also is more structured with specific Federal requirements.

With respect to the second item 42 CFR 405.502(g)(3)(A) requires that a carrier or DMERC proposing to establish a special payment limit for a single service or a number of items and services must first inform CMS, and wait for approval; and then inform the affected suppliers and Medicaid agencies of the proposed payment amounts and the factors it considered in proposing the particular limit.

The related carrier or DMERC notice must also consider the following. Therefore these factors must be determined in the IR determination process.

- The effects on the Medicare program, including costs, savings, overall assignment rates, beneficiary liability, and quality of care.

- What entities would be affected such as classes of providers or suppliers and beneficiaries.

- How significantly would these entities be affected.

- How would the adjustment affect beneficiary access to items or services.

These may be determined in part on fact and in part on judgment. The notice should explain any assumptions and their bases.

Carriers/DMERCs also must evaluate any comments received in response to its notice and notify CMS in writing of any limits that they plan to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification. After the carrier has received CMS' acknowledgement, the carrier must inform the affected suppliers and State Medicaid agencies of any final limits it establishes. The effective date for a final payment limit may apply to services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit

CMS should anticipate an increase in carrier/DMERC costs to perform the analysis and prepare the related notices, but we recommend that you let the normal budget process handle this.

4.1.2 - CMS Central Office Staff

CMS Central Office staff have been addressing the IR area for years. However, there will be some workload increase for developing the proposed and final notices for the IR determinations, for review and approval of carrier IR determinations, and for overall coordination to determine whether any carrier determinations should be expanded to become national determinations.

There will be a major workload increase where surveys are needed to obtains data, because of the new survey requirements. This includes sample design and the actual survey performance.
While ultimate control and responsibility fall on CMS, it is possible to assign part of the survey work to a PSC contractor or to another contractor.

Examples of functions that could be contracted are:

- Data analysis of paid claims to identify outliers to norms and related recommendations about what HCPCS codes to select for IR review.

- Conducting surveys where needed, in accordance with manual guidelines.

- Preparation of data for CMS use for completing certain items on the OMB Form 83I - the OMB burden clearance form. These are items 13 (hours), 14 (dollars),

and the supporting statement for item 17 (statistical methods). The remainder of the items on Form 83I can be expected to remain rather constant. See http://www.hhs.gov/oirm/infocollect/exhibita.html for related requirements. This form is required for every survey.

See §6 for a description of PSC capabilities that could be used for IR processes. Note that many contractors other than PSCs have similar capability, and that many of these have IDIQ (Indefinite Deliverable, Indefinite Quantity) contracts or the equivalent with CMS.

4.2 - Development of Resources for Information

In a number of places the regulations require use of information not readily available. These include:

- Changing technology or increased facility with technology,
- Production costs and changes in production costs, and
- Manufacturer mark up to suppliers,

In addition CMS may find it appropriate to initiate a national relationship to facilitate getting

- Information from the Federal Supply Schedule,
- Information about the prices VA pays suppliers for items and services, and
- Information from commercial source, such as Supplyline® about manufacturer, wholesaler, or retailer prices.

  Note: Supplyline® is a database, developed by Owens Healthcare, Inc., that categorizes similar products using supplier catalogs and other data (primarily purchase data furnished by clients). It contains two levels of product comparisons: functional product equivalents and alternate products. Functional equivalence is defined as products that have the same product specifications, regardless of manufacturer. Alternate products are products, regardless of manufacturer, that have similar specifications and could be utilized as a substitute. Price data is included for each product.

4.3 - Planning for Preparation of the Federal Register Notices That Are Required

Federal register notices are required by §1842(b)(9) and 42 CFR.502(h) as follows. There are also notice requirements placed on the carriers and DMERCs for their IR determinations. Related requirements are in the IOM, Claims Processing Manual, Chapter 23, §§90

4.3.1 - General CMS Notice Requirements

A proposed notice and a final notice are required announcing plans for a new limit after analysis and before adopting the new limit. These notices set forth the criteria and circumstances, if any, under which a carrier may grant an exception to a payment limit for a category of items or services. There are no other special requirements for the Federal notices unless it is planned to increase or decrease a current limit by more than 15% from the payment for the preceding year.

4.3.2 - Adjustment More Than 15%

If a payment limit is to be adjusted more than 15% then the proposed notice must:

- Explain the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

- Specify the proposed payment amount or methodology to be established for a category of items or services;

- Explain the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

- Explain the potential impacts of a limit on a category of items or services on quality, access, beneficiary liability, assignment rates, and participation of suppliers; and

- Allow no less than 60 days for public comment on the proposed payment limit for the category of items or services.

The final notice must:

- Explain the factors and data that CMS considered, including the economic justification for any uniform fee or payment limit established; and

- Respond to the public comments.

4.3.3 - Adjustment Is 15%

Although the notice requirements where the change is 15% are minimal we recommend that the proposed notice allow 60 days for comment and that it:

- Explain the factors and data that CMS considered in determining that the payment amount for a category of items or services is grossly excessive or deficient;

- Specify the proposed payment amount or methodology to be established for a category of items or services; and
- Explain the factors and data that CMS considered in determining the payment amount or methodology, including the economic justification for a uniform fee or payment limit if it is proposed;

All of these should be readily available from the analysis of the proper payment amount.

Analysis of the impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers may be more difficult and more costly, or otherwise may be administratively more difficult.

4.3.4 - Adjustment Less than 15%

42 CFR 405.502(g) (1)(ii) specifies that an adjustment of less than 15% is not considered grossly excessive or deficient. If an adjustment is over 15% but it is decided that the change will be phased in over multiple years at less than 15% the change is considered over 15%.

4.3.5 - Payment Adjustments Exceeding $100 Million Per Year

For CMS initiated adjustments, CMS will publish in the Federal Register an analysis of payment adjustments that exceed $100 million per year in compliance with Executive Order 12866. If CMS makes adjustments that have a significant effect on a substantial number of small entities, it will publish an analysis in compliance with the Regulatory Flexibility Act.

5 - Planning for Publication of IR Determinations on the CMS Web Site

5.1 - CMS Notices

All proposed notices and final notices are now published on the CMS Web site at http://www.cms.hhs.gov/regulations/. They are retained here for a limited period. They are also published on the GPO Web Page at http://www.gpoaccess.gov/fr/index.html.

Neither site is very useful for a provider or contractor with a need to know the background for an IR determination. We recommend that a copy of each notice file also be placed in a separate folder on the CMS Web site and that an ASP index page be created/published that will hyperlink to the file. An example follows:

HCPCS Code	Issuer of Determination	Description of Item or Service	Date of Publication	View File

This would require no more than 6 or 8 hours to set up and less than half hour to update when a new file is available. Note that a viewable PDF file is routinely made for the GPO page and that this file can be duplicated and used also for this purpose. Carriers can be asked to submit MSWord files that can be converted to PDF in just a few minutes and used.

We recommend accessing the page by adding a line to the "Billing and Payment" section of
http://www.cms.hhs.gov/providers/general_info.asp. We would use the wording "Inherent Reasonableness Determinations."

5.2 - Carrier Notices

See §4.1.1 for notices that carriers must issue. Carrier IR determinations should be included on the national Web site also. Our recommended process flow is for the carrier to prepare the communication to Central Office required in §4.1.2 in format that CMS can add to the site. The carrier can be identified in the second column of the index page. This is addressed in the draft IOM.

6 - Use of PSC Contractors or Other Contractors in the Process

The statute is silent about who can make an IR determination. Regulations at 42 CFR 405.502(g)(1)(ii) specify that CMS or a carrier may make such determinations.

However, PSC contractors have data processing capability and access to claims history files from both CMS and carriers/intermediaries. In addition their function and workload is to array and analyze the same data that must be used for IR determinations.

PSCs could be very useful in computer data analysis to identify HCPCS codes with wide ranges of charges, and for selecting samples for surveys. Also, if a task order can be created that would allow management of workload, PSCs could obtain the necessary staff to handle the other aspects of surveys, e.g., mail handling, phone calls, and tabulating results for CMS professional analysis and final decisions.

See http://www.cms.hhs.gov/PROVIDERS/PSC/PSCWEBP2.ASP for a description of the PSC program.

There also may be other contractors that could provide the logistic support needed. The procedures for CMS to provide authority to specified contractors to use CMS data for specified purposes are relatively simple and provide adequate safeguards for beneficiary information.

7 - Preparation and Release of IOM Instruction to the Contractors, Providers, and Suppliers

A draft IOM manual section is attached. Note that the IOM design contains a placeholder for IR Determinations in §90 of Chapter 23, "Fee Schedule Administration and Coding Requirements," in the Medicare Claims Processing Manual. So we numbered the draft accordingly.

8 - Sources of Claims Information for CMS IR determinations

There are three basic sources of claims information.

- CMS paid claims data in the NCH or NMUD when implemented;
- Carrier files; and
- PSC files.

8.1 - CMS Paid Claims

CMS paid claims data is a database of all paid claims, and includes information from the claims form and selected information about claims processing that carriers and intermediaries report to CWF. The CWF forwards files of individual claims records through a CFWQA process to the database. The record have been edited.

The main disadvantages of this file for IR analysis are:

- It takes some time for the claims to get processed to the database and become available (30-60 days or more);
- The file is so large that computer operations require considerable time to get the data you want; and
- Files sizes after selection of data are still sufficiently large that in many case use of a PC to analyze data is not feasible without careful consideration of reduction of the sample size.

Its primary strength, which is considerable, is that the data are complete with respect to including all paid claims for all beneficiaries. Denials are not now included but may be included in the future.

8.2 - Carrier Files

Carrier files contain the same information that is in CMS files except only for claims processed by that carrier. They will be useful for carrier-wide IR determinations but not for national determinations.

8.3 - PSC Files

PSC files are somewhere between the carrier files and CMS files. PSCs usually function for multiple carriers and intermediaries, and therefore have more files than for single carriers or intermediaries.

PSCs have access to the CMS data that would be needed for IR determinations. This is because part of their function is to perform analysis of individual provider or suppler data against national "norms " Use of the PSC would entail a task modification, but not a very complicated one.

9 - Surveys

For some IR determinations information will not be readily available. In such cases it is necessary to resort to surveys to obtain the detailed information required. It is not required that there be a survey, but any surveys must comply with the following.

The CMS coordinates with GAO and OMB in the design of surveys to providers, suppliers, manufacturers, etc. GAO is concerned with consistency and clarity. OMB is concerned with protecting the public from duplicative and/or unnecessary surveys. CMS must clear future surveys from CMS **or from contractors** with both agencies

GAO's analysis of the IR process in a General Accounting Office report, which was required by §223 of the Balanced Budget Refinement Act of 1999, concluded that there were weaknesses in CMS' contractors' survey process. GAO recommended and CMS agreed that surveys be made using written survey instruments and that the sample selection be reflective of the general population. The intent behind using written survey instruments is to assure that the data collected are consistent and comparable between contractors

In addition to GAO concerns about surveys there are Office of Management and Budget requirements that must be met. Form 83I must be completed by the surveyor and submitted to OMB through CMS for approval. Federal Regulations at 5 CFR 1320.3(d) provide that this requirement applies to CMS or contractor surveys to 10 or more entities.

Regulations at 42 CFR 405.5029g)(4) require the following for CMS and contractor surveys to assure that reliable data is used.

(i) Develop written guidelines for data collection and analysis;

(ii) Ensure consistency in any survey to collect and analyze pricing data.

(iii) Develop a consistent set of survey questions to use when requesting retail prices.

(iv) Ensure that sampled prices fully represent the range of prices nationally.

(v) Consider the geographic distribution of Medicare beneficiaries.

(vi) Consider relative prices in the various localities to ensure that an appropriate mix of areas with high, medium, and low consumer prices was included.

(vii) Consider criteria to define populous State, less populous State, urban area, and rural area.

(viii) Consider a consistent approach in selecting retail outlets within selected cities.

(ix) Consider whether the distribution of sampled prices from localities surveyed is fully representative of the distribution of the U.S. population.

(x) Consider the products generally used by beneficiaries and collect prices of these products.

(xi) When using wholesale costs, consider the cost of the services necessary to furnish a product to beneficiaries.

Survey design and execution methodologies implementing the above requirements are in §90.5 of the IOM draft manual..

10 - Continuing Review of the Applicability of IR Determinations

If CMS or a carrier\DMERC makes a payment adjustment of more than 15 percent spread over multiple years, CMS or the carrier/DMERC will review market prices in the years subsequent to the year that the initial reduction is effective in order to ensure that further changes (reductions or increases) continue to be appropriate.

11 - Draft IOM Sections

See file entitled REVclm104c23s90_v2.doc