CMS Manual System

Pub. 100-04 Medicare Claims Processing

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

Transmittal 000 **Date: XXXXX NN, NNNN**

CHANGE REQUEST 3375

I. SUMMARY OF CHANGES: This transmittal updates instructions for Inherent Reasonableness (IR) determinations .

NEW/REVISED MATERIAL - EFFECTIVE DATE: Xxxx 1, 2004
IMPLEMENTATION DATE: Xxxxx 1, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply only to the red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will only receive the new/revised information, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:
(R = REVISED, N = NEW, D = DELETED)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N	Chapter 23 / Table of Contents
R	Chapter 23 / Section 90 / Inherent Reasonableness

***III. FUNDING:** These instructions shall be implemented within your current operating budget.

IV. ATTACHMENTS:

X	**Business Requirements**
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification

***Medicare contractors only**

Attachment - Business Requirements

Pub. 100-04	Transmittal: nnn	Date: Whenever	Change Request xxxx

SUBJECT: Inherent Reasonableness Determinations

I. GENERAL INFORMATION

A. 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.

Any changes in payment amounts are prospective, i.e., for future service dates. 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. Adjustments of less than 15% will not be made. Adjustments of over 15% are phased in at no more than 15% per year.

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 solicit comments before making a final determination and to inform the affected suppliers and Medicaid agencies of the proposed amounts and the related rationale at least 60 days before implementation.

The determination must consider and the notice must describe the potential impact on quality, access, beneficiary liability, assignment rates, and participation of suppliers.

This instruction provides guidelines for application of the process for making and implementing inherent reasonableness determinations under these provisions.

B. Policy: This instruction provides guidelines for application of the process for making and implementing inherent reasonableness determinations under these provisions. 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.

Carriers/DMERCs are not precluded from making IR determinations on services and items for which CMS has made national fees, but coordination with CMS is required on all IR determinations. A national CMS E mail address has been established for this purpose, and is included in these instructions.

The decision to make an IR determination rests with the carrier, DMERC or CMS. Providers and suppliers have no appeal rights, and may not force a carrier, DMERC or CMS to make an IR determination. However, providers and suppliers may provide information that would lead the carrier, DMERC or CMS to conclude that an IR determination would be appropriate. Any such requests received in writing are considered correspondence until a decision is made about whether to initiate an IR determination.

C. Provider Education: Carriers and DMERCs are to inform suppliers, medicaid agencies, and intermediaries through the normal communication processes when IR determinations are made.

Carriers and DMERCs are to inform suppliers that may be affected by IR determinations that CMS has published instruction standardizing the process and that these instructions are in the CMS Claims Processing Manual, Chapter 23, Section 90. The Claims Processing Manual Table of Contents website address is: http://www.cms.hhs.gov/manuals/104_claims/clm104index.asp

Also the Revision Transmittal can be found at http://www.cms.hhs.gov/manuals/transmittals Click on CR number 3375 in the far right column when you get there.

This notification should be done in your next regularly scheduled bulletin or in a listserve message.

II. BUSINESS REQUIREMENTS

“Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

1	Carriers and DMERCs shall review current policies and procedures for making and effectuating IR determinations to determine what changes must be made to be compliant with the procedures in this transmittal	Carriers and DMERCS
2	Carriers and DMERCS shall change polices and procedures related to IR determinations for ambulance, DMEPOS, laboratory, and drugs as described in the following.	Carriers and DMERCS
3	Carriers and DMERCs shall issue notices to affected suppliers about planned changes in payment amounts resulting from Inherent Reasonableness (IR) determinations.	Carriers and DMERCS
4	Carriers and DMERCs shall consult with suppliers and consider comments received in response to notices about planned changes in payment amounts	Carriers and DMERCS
5	Carriers and DMERCs shall issue final notices responding to the comments and informing suppliers about the changes in payment amounts 60 days prior to implementation.	Carriers and DMERCS
6	Carriers and DMERCs shall consider standard factors in making IR determinations as described in §§90 of Chapter 23 of the Medicare Claims Processing Manual	Carriers and DMERCS
7	Carriers and DMERCs shall structure any surveys or computer analyses needed for data to support IR determinations so that areas are grouped for analysis by - high, medium or low consumer prices, - populous or less populous areas, and - urban or rural. CMS will furnish a zip code file that classifies each zip code, for carriers and DMERCs to use for this purpose.	Carriers and DMERCS
8	Carriers and DMERCs shall send proposed survey questions and supporting information to CMS for CMS coordination with OMB and GAO, and for CMS approval before implementing the survey.	Carriers and DMERCS
9	Carriers and DMERCs shall coordinate with CMS before starting an IR determination process to permit CMS to determine whether the determination should be national or local and to avoid duplication among carriers.	Carriers and DMERCS

10	Carriers and DMERCs shall forward final notices to CMS for review and approval before releasing them to suppliers.	Carriers and DMERCS

III. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions: N/A

X-Ref Requirement #	Instructions
N/A	N/A

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date: **Implementation Date:** **Pre-Implementation Contact(s):** **Post-Implementation Contact(s**	**Funding for implementation activities will be provided to contractors through the regular budget process.**

Medicare Claims Processing Manual

Chapter 23 - Fee Schedule Administration and Coding Requirements

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90 - Inherent Reasonableness

90.1 - Background and Introduction

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. CMS makes Inherent Reasonableness (IR) determinations for national implementation, and carriers and DMERCs make IR determinations for implementation within their contract area.

The price of 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. Adjustments of 15% or less will not be made. Also, where the adjustment is more than 15%, any change will be implemented in phased in increments of 15% per year based on the initial price from which the adjustment is made, except for the last year of the phase in, in which the price will be adjusted by the remaining balance of the total adjustment.

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

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; and
- 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.

Intermediaries normally would not be involved except for services paid to facilities under a fee schedule, that do not meet these reasons for exclusion. Intermediaries request the carrier (or DMERC for DMEPOS items) to make any IR determinations needed for a local determination or ask CMS central office in cases where the determination should be a national determination.

Carriers and DMERCs will inform intermediaries of all price changes that result from IR determinations, and the related effective date.

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, e.g., use the lower of the related Medicare fee schedule or amount from the Federal Supply Schedule (FSS) if the FSS price is available in the State. Where a special method is used it must be expected that the usual dollar adjustment will exceed 15%.

90.2 - How to Determine an Inherent Reasonableness Determination Is Needed

There are essentially two issues that apply:

- Is the current Medicare payment amount unreasonable (is it grossly excessive or deficient?), and if so;

- What would be a reasonable payment amount (allowed amount)?

The issue is whether the current Medicare payment amount is unreasonable. Any changes in payment amount are prospective. Do not attempt to determine whether past payments were excessive or deficient.

If the current Medicare payment amount seems unreasonable the CMS, the carrier, or the DMERC may begin accumulating related information as described in the following sections. If at any time it is decided that the investigation process will not change the price by 15% or more:

- effort is to be discontinued,

- any related documentation is saved for future use, and.

- the carrier must publish a notice as described 90.7.2 describing the basis for the decision that the price is not expected to change by 15% or more.

90.2.1 - Indications that the Current Price is Excessive or Deficient

An indication that the payment amount determined by current processes for a particular item or service is grossly excessive or deficient may occur in number of ways.

- An OIG or GAO audit may uncover payment anomalies;

- Investigative reporters, Congressional investigations, concerned beneficiaries, or beneficiary family members can all call attention to circumstances that are appropriate for IR review;

- Carrier or intermediary staff may notice in catalogs or trade journals that the item or service has become available at a significantly lower price than the amount payable;
- It may be noticed that the amount payable seems excessive or deficient based on the estimated cost of producing the item or service;
- In the case of a carrier or intermediary, the carrier/intermediary may be requested by CMS to perform an inherent reasonableness determination;
- A supplier may provide information such as that above that indicates to the satisfaction of the carrier or DMERC that further review is warranted, or
- There may be other indicators not enumerated here. Neither CMS nor the carrier/ DMERC is precluded by the absence of one or more of the above from investigating whether a payment amount is grossly excessive or grossly deficient.

These may indicate a need to perform an inherent reasonableness determination. The determination will determine the appropriate payment amount. See §§90.2.2 and §§90.3 - 90.7 respectively for examples of factors that may result in grossly excessive or grossly deficient prices and for instructions for making related IR determinations.

90.2.2 - Examples of Factors That May Result in Grossly Excessive or Deficient Payment Amounts

90.2.2.1 - The Marketplace Is Not Competitive

This includes circumstances in which the marketplace for a category of items or services is not competitive because a limited number of suppliers furnish the item or service. This would be evidenced by a small number of suppliers billing for the item or service as shown in carriers claims records or CMS National Claims History (or National Medicare Utilization Database [NMUD]) when implemented.

In order to consider the market not competitive, it is necessary to determine the total number of suppliers who have billed (or who have been paid for) the item or service. Acceptable sources of data are CMS' National Claims History data and carrier claims history data. This should be a routine analysis in all determinations, to determine whether the factor impacts on the determination.

Generally national data should be used at least for comparison with local data except where carrier or DMERC analysis indicates that local data is sufficient because national distribution of the item or service is not applicable.

National data is requested from CMS at the following E mail address ir_requests@cms.hhs.gov .

90.2.2.2 - Medicare and Medicaid Are the Sole or Primary Sources of Payment for a Category of Items or Services

To determine whether Medicare and/or Medicaid is the sole or primary sources of payment for the item or service CMS National Claims History data for the related HCPCS codes must be compared to total market volume figures. Total market figures are developed by requesting data from suppliers or finding government (e.g., Commerce Department censuses) or commercial sources that measure the total market.

For carrier-wide or Statewide determinations local data must be compared with market figures for the corresponding area. If data for this comparison is not available do not use this factor.

90.2.2.3 - Payment Amounts for a Category of Items or Services Do Not Reflect Changing Technology, Increased Facility With That Technology, or Changes In Acquisition, Production, or Supplier Costs

Experience and knowledge of CMS and contractor physicians and consultants, and experience of other government agencies may provide information about technological advances that would change supplier costs. CMS develops and maintains ongoing relationships with government agencies that provide items and services similar to those Medicare provides, e.g., VA for prosthetic and orthotic devices. A wide variance in the prices VA pays and the Medicare payment amount may indicate technological advances not yet factored into the Medicare amount.

Changes in wholesaler or manufacturer catalog prices may also indicate changes in supplier costs.

The CMS routinely monitors prices paid by the VA and also prices for products listed in the Federal Supply Schedule maintained by VA to detect trends and to identify items for which the payment amount may be grossly excessive or grossly deficient.

90.2.2.4 - Payment Amounts for a Category of Items or Services in a Particular Locality Are Grossly Higher or Lower Than Payment Amounts in Other Comparable Localities for the Category of Items or Services, Taking Into Account the Relative Costs of Furnishing the Category of Items or Services in the Different Localities

Differing payment amounts in different areas can be ascertained by comparing payment amounts for the areas. However, it is important to structure the analysis so that areas are grouped for analysis by:

- High, medium or low consumer prices,

- Populous or less populous, and
- Urban or rural.

CMS has prepared a file that identifies an appropriate stratified cell for each ZIP code. This will be distributed separately via One Time Notice and updated as appropriate. Carriers and DMERCs use this file to identify comparable localities. Use the ZIP code of the beneficiary to determine the appropriate cell.

Sampling techniques appropriate for the analysis may be used with the file. The purpose of the file is to match similar areas for the above criteria.

This file is also used for developing surveys under §90.5.

90.2.2.5 - Payment Amounts for a Category of Items or Services Are Grossly Higher or Lower Than Acquisition or Production Costs for the Category of Items or Services

Most fee schedule were determined in the past and have been updated annually by applicable update factors. This addresses whether or not relation ship of production costs or acquisition costs to the payment amount have changed to the extent that the current payment amount has become grossly excessive or grossly deficient when considering production or acquisition costs. To consider this factor it is necessary to be able to define current production and acquisition costs and relate them to the current payment amount. Although it may be helpful, it is not necessary to compare current production and acquisition costs to these costs when the fee schedule was initially implemented. It is necessary only to compare production costs or acquisition costs to the current payment amount, and reflect on whether the relationship is equitable.

If a survey is used to determine production costs or acquisition costs, see §§90.5 for related survey requirements.

90.2.2.6 - There Have Been Increases In Payment Amounts for a Category of Items or Services That Cannot Be Explained By Inflation or Technology

Similar to § 90.2.2.5, this factor addresses changes since the fee schedule inception (or since the last IR determination if applicable). Should the payment amount appear to have increased or decreased disproportionate to inflation or technology this would be an indicator that the payment amount may be grossly excessive or grossly deficient.

90.2.2.7 - Payment Amounts for a Category of Items or Services Are Grossly Higher or Lower Than the Payments Made for the Same Category of Items or Services by Other Purchasers in the Same Locality

Grossly higher or lower payment by Medicare for the same category of items and services in the same locality by purchasers other than Medicare are an indication that Medicare payments may grossly excessive or grossly deficient.

To consider this factor, compare the Medicare payment amounts to the payment amounts allowed by other purchasers in the locality. Use the locality as defined by the other payers if feasible. If localities among payers are inconsistent develop localities using the ZIP code file described in 90.2.2.4.

90.3 - The IR Decision (Determining A Realistic and Equitable Payment Amount)

Section 90.2§§ describes indicators of grossly excessive or grossly deficient Medicare payment amounts and factors that may result in such. This section and following sections provide instructions on how to determine an appropriate payment amount under an IR determination. CMS makes IR determinations for national implementation, and carriers and DMERCs make IR determinations for implementation within their contract area.

90.3.1 - Coordination with CMS CO

After initial analysis that an IR decision is appropriate the carrier or DMERC shall coordinate with CMS to determine whether the IR determination for the items or services in question is a carrier/ DMERC determination or is a national IR determination. Send an E mail to; ir_requests@cms.hhs.gov to inform CMS of the issues. Include a brief description of the issues and your plans. CMS will respond by E mail and/or phone.

90.3.2 - Factors to Consider in IR Determination

42 CFR 405.502(g) provides that in establishing a payment limit that is realistic and equitable the following factors may be considered. Not all factors will necessarily apply to each inherent reasonableness determination. In such cases only those factors that are applicable and that can be determined will be considered. Also, there may be other factors pertinent for the item or service in question, and if so these factors are used.

A - Price markup - This is the relationship between the retail and wholesale prices or manufacturer's costs of a category of items or services. If information on a particular category of items or services is not available, CMS or a carrier/DMERC may consider the markup on a similar category of items or services and information on general industry pricing trends. To the extent available the following information is used:

- Catalogs from wholesalers and retailers;

- Commercial data;
- Prices paid by VA; and/or
- The Federal Supply schedule.

If insufficient information can be found from theses sources a survey can be considered to ascertain price markup. See §90.5 for special requirements applicable to surveys.

B - Differences in charges - CMS or a carrier/DMERC may consider the differences in charges for a category of items or services made to non-Medicare and Medicare patients or to institutions and other large volume purchasers. This requires comparing the difference in supplier charges between those made to Medicare and those made to other purchasers. Medicare claims charges can be ascertained from claims history. Charges to non Medicare purchasers can be obtained from:

- The supplier;
- Catalogs from suppliers;
- Commercial sources;
- Prices paid by VA; and/or
- The Federal Supply schedule (see §90.4 for a description of the Federal Supply Schedule).

If insufficient information can be found from theses sources a survey can be considered to ascertain charges to payers other than Medicare. See §90.5 for special requirements applicable to surveys.

C - Costs - CMS or a carrier/DMERC may consider resources (for example, overhead, time, acquisition costs, production costs, and complexity) required to produce a category of items or services. To consider this factor, detailed supplier cost information or cost on other items of identical composition would be needed.

If insufficient information can be found from theses sources a survey can be considered. See §90.5 for special requirements applicable to surveys.

D - Utilization - CMS or a carrier/DMERC may impute a reasonable rate of use for a category of items or services and may consider unit costs based on efficient use. For example if the service is performed infrequently it must be determine whether more frequent use of the service is reasonable and if so what the average cost per service would be.

E - Payment amounts in other localities - CMS or a carrier/intermediary may consider payment amounts for a category of items or services furnished in another locality. When this factor is applied, the localities considered should be similar. Data for other localities could come from:

- Within the carrier/intermediary jurisdiction and from carrier records;
- Outside the carrier/intermediary jurisdiction but within the PSC jurisdiction and from PSC records; or
- From CMS national claims data and from CMS process for PSCs to download data.

See §90.5.1.7 for requirements for structuring any surveys that may be necessary.

90.3.3 - Consideration of Potential Impact of Determination

42 CFR 415.502(h) requires CMS or the carrier/DMERC to consider:

- The impact on quality of care;
- Beneficiary access to care;
- Beneficiary liability;
- Assignment rates; and
- Participation of suppliers;

before implementing any inherent reasonableness determination. This applies to local contractor determinations as well as CMS determinations.

When the IR determination is a carrier/DMERC determination the carrier/DMERC 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 to suppliers must also address the following:

- The effects on the Medicare program, including costs, savings, 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.

Carriers also must evaluate any comments received in response to its notice and notify CMS in writing of any limits that it plans 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 must be for services furnished at least 60 days after the date that the carrier notifies affected suppliers and State Medicaid agencies of the final limit.

Carrier/DMERC notification to suppliers may be via list serve, regularly scheduled or special bulletin, posting to a web site, or a combination, to be determined by the carrier/DMERC. The 60 day waiting period starts on the day the first notification is published.

CMS will publish the carrier/DMERC determination on the CMS Web site. See §§ 90.7.

90.3.4 - Coordination With Supplier Industry

42 CFR 405.502(h) requires CMS or carriers/DMERCs to consult with representatives of the supplier industry likely to be affected by the change in the payment amount before making a determination that a payment amount is to be changed.

90.4 - The Federal Supply Schedule

The GSA Federal Supply Schedule (FSS) is somewhat useful in connection with determining prices paid by others, but has shortcomings mainly related to what suppliers are willing to place on the schedule.

The FSS is delegated to the VA. Manufacturers periodically provide the FSS with bid prices for products, and the VA produces a list for agencies that use the FSS for ordering supplies, equipment or DME/POS products. Products are identified by any number desired by the manufacturer (usually inventory ordering number and not HCPCS).

Parts of the schedule are electronic and parts must be requested. Currently Fisher HealthCare has the contract to administer the lab portion and has a Web page at https://www1.fishersci.com/healthcare/fss/index.jsp

The address for requests for nonlab supplies and for other information can be accessed electronically at http://www1.va.gov/oamm/nac/fsss/.

The presence of an item on the FSS indicates that the item is available. Contact with the vendor is then necessary to determine if the item is available in the locality.

Note that the Federal Supply Schedule is somewhat useful in connection with determining prices paid by others, but lists only what suppliers are willing to place on the schedule. Do not expect to find all items listed there

90.5 - Federal Survey Requirements

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 13203(d) provide that this requirement applies to CMS or contractor surveys to 10 or more entities.

These requirements apply to carrier/DMERC surveys as well as to CMS surveys

90.5.1 - Design of Written Survey and Related Coordination

Surveys for individual or groups of items must be designed consistently. The following rules apply for all surveys to achieve consistency.

1 - Surveys must be written, although telephone calls or other communication methods may be used to alert recipients to the receipt of the survey questionnaire.

2 - The same questions must be asked of all recipients. Wording of each separate question must be identical for all recipients. If telephone or other discussion is used identical written "scripts" must be used and must be followed closely.

3 - Prices asked of retailers must include any applicable retail sales taxes (Medicare payment allowances include the retail sales tax.). Wholesale prices or manufacturer prices do not include retail sales tax but do include any applicable shipping charges.

4 - Prices (or costs) requested must specify the items requested are those used for Medicare where there are variances among typical Medicare items and typical non-Medicare items.

EXAMPLE: Enteral formulas must request information on formulas used for tube feeding instead of cans used for oral nutritional supplements.

5 - DMERCs must coordinate with other DMERCS in design of surveys that cover the same items or groups of similar items. Carriers must coordinate with CMS Central Office, to assure that separate carriers are not independently designing surveys for the same item. Send an E mail to ir_requests@cms.hhs.gov explaining the issues and your plans.

6 - When the survey instrument is ready for use it is sent to ir_requests@cms.hhs.gov in CMS Central Office for coordination with GAO and OMB. The DMERC, carrier, or intermediary that designed the survey must include the information in §90.5.2 to assist CMS complete Form 83I for OMB approval on the survey. See §90.5.3, Exhibit 1, for an exhibit of the form. The related general instructions for completing the form can be found at http://www.hhs.gov/oirm/infocollect/exhibita.html. Carriers and DMERCs need not be concerned with the items other than those described in §90.5.2.

7 - Surveys must be structured to include:

- High, medium or low consumer prices,
- Populous or less populous, and
- Urban or rural.

When considering data across localities it is important to structure the analysis so that areas are grouped for analysis by:

- High, medium or low consumer prices,
- Populous or less populous, and
- Urban or rural.

CMS has prepared a file that identifies and compares all national ZIP codes and assigns each ZIP code to particular grouping.. This will be distributed separately via One Time Notice and updated as appropriate. Carriers and DMERCs use this file to identify comparable localities.

Sampling techniques appropriate for the analysis may be used with the file. The purpose of the file is to match similar areas for the above criteria.

If surveys are not returned, or if they are returned in numbers that the carrier/DMERC believe are insufficient to make a valid IR determination, the carrier/DMERC should discuss the situation with CMS (E mail ir_requests@cms.hhs.gov or telephone call to whoever was identified in response to the earlier E mail.)

90.5.2 - Information Contractors Must Furnish to Support Survey Design Clearance With OMB

A copy of Form 83I follows. The CMS will complete the Form for submission to OMB. Contractors must furnish sufficient information to enable completion of items 13, 14, 17. This information is:

Item 13 - Annual recordkeeping and reporting burden:

a. Number of planned respondents to the survey;

b. Total annual response (usually the same as (a) for a one-time survey;

b1. Percentage collected electronically (usually 0%);

c. Total annual hours requested (the estimated total hours for the respondents to do any related research and complete the survey;

d. Current OMB inventory (contractors leave this blank; CMS will complete);

e. Difference (contractors leave this blank; CMS will complete);

f. Explanation of difference (should normally be "program change."

Item 14 - Annual reporting and recordkeeping burden (in thousands of dollars)

a. Total annualized capital/startup costs (will normally be zero);

b. Total annual Costs (O&M) (the contractor enters the estimated total cost for all responders combined to spend the time to obtain and provide the data requested;

c. Total annualized cost requested (the total of 14a and 14b);

d. Current OMB inventory (CMS will enter this);

e. Difference (CMS will enter this);

f. Explanation of difference (CMS will enter this):

1. Program change;

2. Adjustment.

Item 17 - Statistical methods

The contractor should describe the method of selecting survey entities, e.g., x % sample of suppliers that furnished xxxxx HCPCS code as reflected in contractor history records.

90.6 - Consultation With Suppliers

Before making a national determination that a payment amount for a category of items or services is not inherently reasonable by reason of its grossly excessive or deficient amount, CMS consults with representatives of the supplier industry likely to be affected by the change in the payment amount.

This consultation may by solely through the release of a proposed notice, as described in §90.7 or it may include discussion with supplier representatives. Any proposed notice must include the rationale for the change and provide suppliers and other interested parties 60 days to comment. The proposed and final notices must also identify any circumstances under which the carrier may grant an exception to the limit.

Requirements for carrier or DMERC consultation are similar except that the Federal notice process is not used. Instead the carrier or DMERC must issue a bulletin to affected suppliers and allow 60 days for comment. The carrier/DMERC must also inform affected Medicaid agencies.

90.7 - Notification of Results of Inherent Reasonableness Determination

90.7.1 - Required CMS Notices

CMS must issue a proposed notice if its intention to establish a revised payment amount, and a final notice.

The proposed notice:

- Explains 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;

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

- Explains 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;

- Explains the potential impacts of a limit on a category of items or services as described in paragraph (h)(1) of this section; and

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

The final notice:

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

- Responds to the public comments.

The revised payment limit will be effective no sooner than for services furnished 60 days after the date of the final notice.

Both the proposed and final notices will be published on the CMS Web site at: http://www.cms.hhs.gov/regulations/ and on the GPO Web Page at http://www.gpoaccess.gov/fr/index.html.

In addition the final notice will be published and retained on the CMS Web site at http://www.cms.hhs.gov/providers/general_info.asp . Use the "Inherent Reasonableness Determinations" link.

90.7.2 - Required Carrier/DMERC Notices

A carrier proposing to establish a special payment limit for a category of items or services must inform the affected suppliers and Medicaid agencies of the proposed payment amounts, the factors it considered in proposing the particular limit, and solicit comments. The notice must also address the following:

- The effects on the Medicare program, including costs, savings, 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.

The carrier/DMERC also must evaluate the comments it receives on the notice and must notify CMS in writing of any final limits it plans to establish. CMS will acknowledge in writing to the carrier that it received the carrier's notification. After the carrier has received CMS's 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 must 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 will publish the final carrier notice on the CMS IR Web page as shown at the end of § 90.7.1 above.

90.8 - Continuing Review of the Applicability of IR Determinations

If CMS or a carrier makes a payment adjustment of more than 15 percent spread over multiple years, CMS or the carrier (whichever made the IR determination) will review market prices in the years subsequent to the year that the initial change is effective in order to ensure that further changes continue to be appropriate.

90.9 - Informing Intermediaries of IR Determinations

Carries and DMERCs shall inform intermediaries of price changes resulting from IR determinations using their usual process for notifying intermediaries about carrier or DMERC price updates.