Program Memorandum
Intermediaries/Carriers

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

Transmittal AB-02-174 **Date: DECEMBER 3, 2002**

CHANGE REQUEST 2381

SUBJECT: Single Drug Pricer (SDP)

SCOPE: This Program Memorandum (PM) clarifies the instructions contained in PM AB-02-075 by describing a procedure for identifying uniform, consistent payment allowances that are based on 95 percent of the average wholesale price (AWP) for Medicare covered drugs and biologicals (hereinafter "drugs").

This PM applies to all Medicare covered drugs for which the Medicare payment allowance is based on 95 percent of the AWP except for drugs billed to durable medical equipment carriers (DMERCs) and hospital outpatient drugs billed to fiscal intermediaries (FI).

DMERC-paid drugs are excluded because these drug payment allowances are already consistent nationally.

Hospital outpatient drugs (except blood clotting factors) are excluded because the payment allowance for such drugs is determined by a different procedure from that described in PM AB-02-075.

BACKGROUND

Medicare currently covers about 400 drugs that meet the scope of this PM. Examples of drugs to which this PM applies include, but are not necessarily limited to, drugs furnished incident to a physician's services and ESRD drugs separately billable from the ESRD composite rate that are furnished by independent dialysis facilities.

Section 4556 of the Balanced Budget Act (BBA) of 1997 established a new methodology for Medicare to pay for drugs covered under Part B. Under this provision, effective January 1, 1998, Medicare payment for drugs is based on the lower of the actual charge on the Medicare claim or 95 percent of the average wholesale price (AWP). In enacting this legislation, the Congress confirmed the concept of using a single national price by using the AWP, a term which CMS had previously defined in its regulations (42 C.F.R. §405.517) as a national price.

This policy was implemented through regulation and a series of instructions, the latest of which is PM AB-02-075. Although the policy refers to a national payment allowance for each drug, the pricing function was delegated to local carriers and for various unintentional reasons, divergent drug pricing around the country has resulted.

CMS is establishing the SDP to correct identified discrepancies, further the legislative goal of establishing a uniform payment allowance as a reflection of the AWP, and otherwise apply the existing statute and regulation more accurately and efficiently. Under the SDP, CMS will establish prices centrally, thereby resulting in greater consistency in drug pricing nationally. In doing so, CMS will adhere to the current drug pricing methodology explained in PM AB-02-075.

POLICY

1. The CMS establishes a single, national price for each Medicare covered drug whose payment allowance is based on 95 percent of the AWP except for drugs billed to DMERCs and hospital outpatient drugs billed to FIs.

2. The CMS furnishes drug pricing files (hereafter "SDP files") to each Medicare carrier and FI, and regional office (RO) for drugs within the scope of this PM.

3. Each FI and carrier must accept the SDP files made available by CMS and process bills/claims for any drug identified on the files on the basis of the price shown on the applicable file.

4. Each FI and carrier shall continue to apply the procedures in PM AB-02-075 to any drug within the scope of this PM that is not included on the SDP files furnished by CMS, including but not limited to drugs not otherwise classified (NOC).

IMPLEMENTATION

A. On a quarterly basis, CMS will furnish three SDP files to all FIs, carriers, and ROs except regional home health intermediaries and DMERCs, as follows:

   1. "HCPCS" Drug Pricing File

      a. The CMS will furnish a SDP file that contains drugs identified by a code established by the Health Care Procedure Code System (HCPCS). This HCPCS drug pricing file (HDPF) will contain:

         i. every HCPCS drug code for every drug for which claims are submitted to local carriers (excluding DMERCs);
         ii. with respect to each such HCPCS code, the unit of measure by which such HCPCS code is defined;
         iii. with respect to each HCPCS code and unit of measure, the Medicare allowed amount;
         iv. with respect to each HCPCS code for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;
         v. with respect to each new HCPCS code, an indicator to that effect; and
         vi. with respect to each deleted HCPCS code, an indicator to that effect.

      b. The filename of the initial HDPF will be "hdpf0301.xls", with the numeric portion corresponding to the year (2003) and quarter (01) for which the file is applicable. Subsequent versions of the HDPF file will follow this convention.

      c. The first HDPF will be made available on or about December 5, 2002. Thereafter, a complete overlay HDPF will be made available approximately 60 days before the beginning of each calendar quarter, i.e., on or about each February 1st, May 1st, August 1st, and November 1st.

   2. "NOC" Drug Pricing File

      a. The CMS will furnish a SDP file for drugs NOC. This NOC drug pricing file (NDPF) will contain:

         i. with respect to every drug NOC under the HCPCS for which claims are submitted to local carriers (excluding DMERCs), the NDC code and drug name;
         ii. with respect to each such NDC code, the unit of measure by which such drug is covered;

iii. with respect to each NOC drug, the Medicare allowed amount;
iv. with respect to each NOC drug for which the price has changed from the price determined in the previous quarter, an indication as to whether the new price is higher or lower than the price determined in the prior quarter;
v. with respect to each new NOC drug, an indicator to that effect; and
vi. with respect to each deleted NOC drug, an indicator to that effect.

b. The filename of the initial NDPF will be "ndpf0301.xls", with the numeric portion corresponding to the year (2003) and quarter (01) for which the file is applicable. Subsequent versions of the NOC file will follow this convention.

c. The first NDPF will be made available on or about December 5, 2002. Thereafter, a complete overlay NDPF will be made available approximately 60 days before the beginning of each calendar quarter, i.e., on or about each February 1st, May 1st, August 1st, and November 1st.

Note To FIs: The NOC file does not necessarily contain all NOC drugs. Contact local carriers to determine if there are other drugs they have priced separately and request the prices for those drugs if needed.

3. The CMS will furnish a pricing documentation file (PDF) that contains:

   a. The data in the drug pricing file, i.e., each HCPCS code and its Medicare allowed amount;

   b. With respect to each HCPCS drug code, every product, as identified by its NDC code, that contains the same active ingredient as specified in the definition of the HCPCS code;

   c. With respect to those NDC codes used to determine the Medicare-allowed amount, an indicator to that effect;

   d. With respect to each such NDC, the price or prices used to determine the average wholesale price (AWP) of the product;

   e. With respect to each such price, an identification of the source(s) of the price; and

   f. With respect to each such source, the date, edition, and other information necessary and sufficient to enable CMS to verify the price.

B. Except as specifically noted, each FI and carrier will:

1. **Within 24 hours** of the receipt of this PM, furnish to CMS an e-mail address to which the above-mentioned files may be sent, a contact person at the contractor, and your RO contact. Furnish such notice to SDP@cms.hhs.gov.

2. Upon receipt of an e-mail from CMS containing the SDP files, to be sent on or about December 5, 2002, download the SDP files.

3. Execute your normal update process using the SDP files. Process manually if necessary to implement SDP files' prices effective January 1, 2003.

4. Compare the prices you paid previously with the prices shown on the initial SDP files. Take note of the unit pricing quantity shown on the applicable SDP file and compare it to your unit pricing quantity to ensure that any apparent price changes are real. Notify physicians of price changes in the manner you have done previously.

5. Effective January 1, 2003, pay drug claims on the basis of the prices shown on the SDP files. Ensure that your unit pricing quantity is the same as that shown on the applicable file.

6. Upon receipt of subsequent e-mails from CMS, to be sent approximately 60 days before the beginning of each calendar quarter, download the updated SDP files and update your prices at the beginning of each following calendar quarter thereafter on the basis of the prices shown on the updated SDP files.

7. Execute your normal update process using the SDP files. Process manually if necessary to implement SDP files' prices effective with the beginning of the following quarter.

8. Note the price changes on each quarterly SDP file and note all price changes. Carriers: Notify physicians of price changes on a quarterly basis in the manner you have done previously. FIs: Notify ESRD facilities (with respect to ESRD drugs not included in the composite rate) and hospitals (with respect to clotting factors) of price changes to the extent and in the manner you have done previously.

9. Advise your RO concerning any price on a SDP file that you believe is erroneous.

10. Do not substitute your price for the price shown on an SDP file unless authorized to do so by a joint memorandum from CMS.

11. If updated prices, in whole or in part, are not made available on a timely basis, use the prices from the prior quarter's SDP files to the extent necessary.

12. Carriers only: Continue to implement PM AB-02-075 with respect to any drug that is not listed on the SDP files and with respect to any compounded drug that is not identified by a single National Drug Code (NDC).

13. Carriers only: On or before March 1st of each year, report to your RO whether you are then pricing any drugs separately, including but not limited to NOC drugs. If you are then pricing one or more drugs separately, then also include in the report the name of the drug, its NDC, the price you determined, and the source you used to price drug.

14. FIs: As needed, on a quarterly basis and within 7 days of receipt of the SDP files, request from carriers prices of drugs that they may price separately. Carriers: Upon request, on a quarterly basis and within 7 days of any such request, furnish to FIs within your jurisdiction, free of charge, the subset of your files, which includes drugs that you price separately.

15. Respond to questions about price changes as you have done previously. Respond to questions about the implementation of the AWP pricing methodology, as you have done previously. Respond to questions about the SDP on the basis of these instructions. Refer any questions that you cannot answer to your RO.

C. Each RO will:

1. Advise carriers concerning the implementation of this PM.

2. Respond to questions about drug price changes as you have done previously.

3. Respond to questions about the implementation of the AWP pricing methodology as you have done previously.

4. Respond to questions about the SDP on the basis of these instructions.

5. Refer any questions that you cannot answer to central office (CO) per item 6, below.

6. Advise CO of matters addressed by this PM that require CO attention**.** With respect to the matters addressed in items B.9 and B.13 of the Implementation section, forward the information to: sdp@cms.hhs.gov

PROVIDER EDUCATION

1. Carriers: Must publish the attached article and SDP prices in your next regularly scheduled bulletin and post the article and SDP prices on your Web site immediately. Carriers are waived from the requirement to give 30 days advance notice for fee schedule changes.

2. FIs: Must develop a similar article with respect to blood clotting factors administered in a hospital outpatient department and ESRD drugs (separately billable from the composite rate that are furnished by independent dialysis facilities) and publish such article in your next regularly scheduled bulletin and post the article and SDP prices on your Web site immediately.

The *effective date* for this PM is December 3, 2002.

The *implementation date* for this PM is December 3, 2002. The *implementation date* for paying claims based on the SDP prices is January 1, 2003.

These instructions should be implemented within your current operating budget.

This PM may be discarded after January 1, 2004.

Contact your RO if you have any questions.

Attachment

Attachment

Standardizing Prices for Medicare Covered Drugs

On January 1, 2003, the Centers for Medicare & Medicaid Services (CMS) will be implementing a single drug pricer (SDP) for drugs and biologicals (hereinafter "drugs") with respect to drugs covered under Medicare Part B and priced by local carriers.

In the past, CMS has received much criticism concerning excessive expenditures related to the payment rates for the approximately 400 drugs that are currently paid based on 95% average wholesale price (AWP); i.e., physicians' offices, outpatient hospitals, dialysis centers, etc. Currently, this payment rate is set at 95 percent of the drug's AWP; however, these payments have sometimes varied depending upon the individual local carrier's application of the payment methodology. Accordingly, CMS is establishing the SDP to correct identified differences amongst its local carriers and is establishing a uniform Medicare payment allowance as contemplated by the regulation (42 C.F.R. 405.517). Drug prices will be established centrally and will be more closely monitored. As a result, physicians and other practitioners will each receive the same payment for the same drug regardless of where their claim for the drug is submitted.

CMS will continue, in accordance with its longstanding practice, to set a price for each drug based on 95% of AWP, and will continue to rely on published compilations (e.g., *RedBook* and *First Data Bank*) to identify wholesale drug prices. Carriers, with the exception of DMERCs, and fiscal intermediaries will be furnished with drug pricing files from CMS and will begin processing claims they receive, for each drug identified on the file, on the basis of the prices shown on these files.

CMS believes that this initiative reflects an innovative approach to resolving some of the problems relating to the pricing of Medicare-covered drugs.