CMS Manual System Pub. 100-04 Medicare Claims Processing	Department of Health & Human Services (DHHS) Centers for Medicare & Medicaid Services (CMS)
Transmittal 35	Date: NOVEMBER 28, 2003
	CHANGE REQUEST 2755

I. SUMMARY OF CHANGES: The minimum standard for the number of pricing files that must be maintained by carrier standard systems for determining the Single Drug Pricer is five fee screens/pricing files.

NEW/REVISED MATERIAL - EFFECTIVE DATE: January 1, 2004 *IMPLEMENTATION DATE: January 1, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED – (Only One Per Row.)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	17/20.1/ Minimum Number of Pricing Files That Must be Maintained Online
	for SDP

*III. FUNDING:

These instructions should be implemented within your current operating budget.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification

^{*}Medicare contractors only

20.1 - Single Drug Pricer (SDP)

(Rev. 35, 11-28-03)

AB-02-174, B-03-059, AB-03-047

Effective January 1, 2003, contractors pay drug claims on the basis of the prices shown on the SDP files, if present.

On a quarterly basis, CMS furnishes three SDP files to all FIs, carriers, and ROs except regional home health intermediaries (RHHIs) and durable medical equipment regional carriers (DMERCs), as follows:

1. "HCPCS" Drug Pricing File

- a. CMS furnishes 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) contains:
 - Every HCPCS drug code for every drug for which claims are submitted to local carriers (excluding DMERCs);
 - With respect to each such HCPCS code, the unit of measure by which such HCPCS code is defined;
 - With respect to each HCPCS code and unit of measure, the Medicare allowed amount:
 - 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;
 - With respect to each new HCPCS code, an indicator to that effect; and
 - with respect to each deleted HCPCS code, an indicator to that effect.
- b. The filename convention is as follows: (1) "hdpf" in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., hdpf0301.xls).
- c. An HDPF will be made available approximately 60 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.
- 2. "Not otherwise classified" (NOC) Drug Pricing File
 - a. CMS furnishes a NOC SDP file for drugs "not otherwise classified." This NOC

drug pricing file (NDPF) contains:

- 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;
- With respect to each such NDC code, the unit of measure by which such drug is covered;
- With respect to each NOC drug, the Medicare allowed amount;
- 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;
- With respect to each new NOC drug, an indicator to that effect; and
- With respect to each deleted NOC drug, an indicator to that effect.
- b. The filename convention is as follows: (1) "ndpf" in the first 4 positions (2) positions 5-8 correspond to the year and quarter for which the file is applicable (e.g., the initial NOC file's filename was "ndpf0301.xls").
- c. The CMS makes a revised NDPF available approximately 60 days before the beginning of each calendar quarter, i.e., on or about each February 1, May 1, August 1, and November 1.

NOTE TO FIs: The NOC file does not necessarily contain all NOC drugs. FIs must contact local carriers to determine if there are other drugs the carrier has priced separately and request the prices for those drugs as needed.

- 3. The CMS furnishes 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.

Except as specifically noted, each FI and carrier will:

- Upon receiving the quarterly update files, execute its normal update process using the SDP files. If necessary, the contractor shall process manually to implement SDP file prices effective with the beginning of the following quarter.
- Compare the prices it paid previously with the prices shown on the prior SDP file; taking note of the unit pricing quantity shown on the applicable SDP file and comparing it to the unit pricing quantity to ensure that any apparent price changes are real.
 - o Carriers must notify physicians of price changes.
 - FIs must 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.
- Advise the RO of any price on a SDP file it believes is not correct.
- Not substitute its price for the price shown on an SDP file unless authorized to do so by a joint memorandum from CMS.
- 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.
- Carriers continue to price drugs as outlined in §20.2 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 NDC.
 - Report to the RO, on or before March 1 of each year, whether any drugs are being priced separately, including but not limited to NOC drugs. If one or more drugs are being priced separately, then the name of the drug, its NDC, the price determined, and the source used to price drug must also be included in the report.
- Carriers and FIs: Publish current SDP prices on their Web site immediately upon receipt of the file from CMS.
- FIs: As needed on a quarterly basis and within seven days of receipt of the SDP files, request, from carriers, prices of drugs that carriers may price separately.
 - Carriers: Upon request, on a quarterly basis and within seven days of any such request, furnish to FIs within jurisdiction, free of charge, the subset of files, which includes drugs that are priced separately.

- FIs and Carriers: Respond to questions about price changes and the implementation of AWP pricing as done previously. Contractors respond to questions about the SDP on the basis of these instructions. Questions that cannot be answered should be referred to the RO.
- Carrier shared systems shall maintain five fee screens/pricing files (a current period and four prior periods) for Part B "incident to" drugs billed to carriers for payment on a fee-for-service basis.
- Since they post the updated SDP file to their Web site upon receipt from CMS, carriers are waived from the requirement to give 30 days advance notice for fee schedule changes with respect to drugs.
- SDP does not preclude the use of inherent reasonableness or the establishment of local medical review policies, including the use of a least costly alternative.
 - o If a least costly alternative is determined and a process for the least costly alternative exists on the SDP, the SDP price for the least costly alternative must be used.
- Medicare coverage determinations are independent of the SDP. The presence or absence of a price for a particular drug in the SDP is irrelevant to Medicare coverage determinations.
- EPO=Q codes are included in the SDP, applicable to physician claims. The statutory limit for EPO applies to nonphysician claims.
- "Unit Measurement" means the amount of whatever measurement is used in the code description (e.g., milligrams (mg)).

ROs:

- 1. Advise carriers concerning the implementation of the SDP.
- 2. Respond to questions about drug price changes.
- 3. Respond to questions about the implementation of the AWP pricing methodology.
- 4. Respond to questions about the SDP on the basis of these instructions.
- 5. Refer any questions that cannot be answered to central office (CO) per item 6, below.
- 6. Advise CO of matters that require CO attention.
- 4. Minimum Number of Pricing Files That Must Be Maintained Online for SDP

 The minimum standard for the number of pricing files that must be maintained by

carrier standard systems for determining the single drug pricer is five fee screens/pricing files (a current period and four prior periods) for Part B "incident to" drugs billed to carriers for payment on a fee-for-service basis.