Process and Information Required to Determine Eligibility of Drugs and Biologicals for Transitional Pass-Through Payment Under the Hospital Outpatient Prospective Payment System (OPPS)

(Effective January 1, 2002)

Please note: For process and information required to apply for assignment and payment for **new technology service APCs or for additional device categories** go to the main OPPS web page, currently at http://cms.hhs.gov/regulations/hopps/default.asp or http://cms.hhs.gov/medlearn/refopps.asp to see the latest instructions.

This announcement describes in detail the process and information required for applications requesting transitional pass-through payment for drugs and biologicals under the Medicare hospital outpatient prospective payment system (OPPS). These instructions apply solely to requests submitted **on or after January 1, 2002** for transitional pass-through payment for drugs and biologicals.

Because CMS intends to make information used in the rate setting process under the OPPS available to the public for analysis, applicants are advised that any information submitted, including commercial or financial data, is subject to disclosure for this purpose.

We will accept transitional pass-through applications for drugs and/or biologicals on an ongoing basis. However, we must receive applications sufficiently in advance of the first calendar quarter in which transitional pass-through payment is sought to allow time for analysis, decision-making, and computer programming. The table below indicates the earliest date that pass-through status could be implemented once a completed application and all additional information are received.

CMS Must Have Complete Application and All Necessary Information by the first business date in	**Earliest Date To Be Considered For Pass-Through Status Effective. . .**
March	July 1
June	October 1
September	January 1
December	April 1

A longer evaluation period may be required if an application is incomplete or if further information is required upon which to base a determination of pass-through eligibility. An application is not considered complete until—

- All required information has been submitted, AND
- All questions related to such information have been answered.

BACKGROUND:

Section 1883(t)(6) of the Social Security Act provides for temporary additional payments or "transitional pass-through payments" for certain innovative devices, drugs, and biologicals. Transitional pass-through payments are required for new drugs and biologicals that were not being paid for as a hospital outpatient service as of December 31, 1996 and whose cost is "not insignificant" in relation to the OPPS payment for the procedures or services associated with the new drug or biological. Under the statute, transitional pass-through payments are to be made for at least 2 years but not more than 3 years. Transitional pass-through payments for drugs and biologicals under the OPPS are discussed in the final rule published in the April 7, 2000 Federal Register (65 FR 18478), and in subsequent OPPS rules and issuances, which can be found at http://cms.hhs.gov/regulations/hopps/default.asp, http://cms.hhs.gov/medlearn/refopps.asp, and http://cms.hhs.gov/manuals/memos/.

REQUIRED INFORMATION:

The information in items 1-10, below, is required in every application for pass-through payment for a drug or biological. An application that does not include the following information is considered incomplete and cannot be acted upon:

1. The trade name and generic name of the product.
2. A detailed description of the clinical application of the product:
    a. What it is and what it does.
    b. The form in which it is supplied (i.e., solution, tablet, etc.).
    c. Method of administration (intramuscularly, intravenously, orally, subcutaneously, sublingually, etc.).
    d. Manner of packaging (indicate dosages/concentrations per ml, per tablet, per mCi, etc.).
    e. The usual minimum dosage per day for one patient.
    f. The usual maximum dosage per day for one patient.
    g. The Healthcare Common Procedure Coding System (HCPCS) code(s), if any, used to identify the product. Specifically, which code(s) is/are used to report the use of this drug or biologic to third party payers? (NOTE: APPROVAL OF A DRUG OR BIOLOGICAL FOR A TRANSITIONAL PASS-THROUGH PAYMENT UNDER THE OPPS IS NOT CONTINGENT ON PRIOR ASSIGNMENT OF A NATIONAL HCPCS CODE.)
    h. How dosages are measured.
3. A copy of the most recently published average wholesale price (AWP), including the date of publication.
4. The current cost of the drug or biological to hospitals, that is, the actual cost paid by hospitals net of all discounts, rebates, and incentives in cash or in kind. In other words, submit the best and latest information available that provides evidence of the actual cost to hospitals for a specific drug or biological specified in terms of dosage and concentration.

5. The date of sale of first unit.
6. Usage (i.e., projected volume) by site of service (i.e., inpatient, outpatient, physician office, etc.).
7. A copy of the Food and Drug Administration (FDA) approval/clearance letter for the product.
8. A copy of the package insert.
9. Name(s), address(es), e-mail addresses and telephone number(s) of the party or parties making the request and responsible for the information contained in the application. If different from the requester, give the name, address, e-mail address, and telephone number of the person that CMS should contact for any additional information that may be needed to evaluate the application.
10. Other information as CMS may require to evaluate a specific request or that the applicant believes CMS may need to evaluate the application.

• Note that a separate application is required for each distinct drug or biological included in a request. For example, if an applicant requests transitional pass-through status for five new drugs, the required information listed above must be completed for each of the five drugs.

WHERE TO SEND APPLICATIONS

Because of staffing and resource limitations, we cannot accept applications by facsimile (FAX) transmission or by e-mail. Mail three copies of each completed application to the following address:

OPPS Pass-Through Applications Division of Outpatient Care Mailstop C4-05-17 Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244-1850

Questions pertaining to the pass-through payment application process for drugs and biologicals may be sent via e-mail to the Division of Outpatient Care mailbox, OutpatientPPS@cms.hhs.gov.

Last modified 10/10/02