

for Q0081, Q0083, Q0084, and Q0085 to facilitate accurate payments for drugs and drug administration.

- Change the status indicator and payment amount for P9010 by assigning it to APC 0957 (Platelet concentrate) with a payment rate of \$37.30.

- Establish new payment bands for new technology APCs.

#### *D. Public Comments and Responses to the August 12, 2003 Proposed Rule*

We received approximately 876 timely items of correspondence containing multiple comments on the August 12, 2003 proposed rule. Summaries of the public comments and our responses to those comments are set forth below under the appropriate section heading of this final rule with comment period.

We received comments from various sources including but not limited to health care facilities, physicians, drug and device manufacturers, and beneficiaries. Hospital associations and the Medicare Payment Advisory Commission (MedPAC) generally supported our proposed approach to revising the relative weights for APCs. Pharmaceutical and medical device manufacturers and some individual hospitals that furnish particular devices or drugs were concerned with the proposed reductions in payment for medical devices and drugs. We received many thoughtful comments from a wide range of commenters with regard to methodological issues in OPPS. In addition, several comments provided external data to support their assertions. The following are the major issues addressed by the commenters:

- The proposal to use \$150 as the packaging threshold for separate payment of drugs.
- The proposal to pay for orphan drugs within the OPPS, basing payment on claims data.
- The proposal to pay for generic drugs at 43 percent of average wholesale prices (AWP) beginning with the time of the generic drug's Food and Drug Administration (FDA) approval.
- The proposed payments for blood and blood products under OPPS.
- The proposal to establish a separate outlier pool for community mental health centers (CMHCs). The proposal to apply an adjustment to increase payment to small rural hospitals' clinic and emergency room (ER) visit rates to ameliorate the effect of the sunseting of the transitional corridor payments.
- The proposal to reinstitute drug and device coding requirements.
- Propose APC assignments and status indicators for numerous services.

In addition to comments regarding the policy proposals in the August 12, 2003 proposed rule, we received comments about the publication date of the proposed rule and the comment period.

*Comment:* Some commenters objected to the use of the date on which the August 12, 2003 proposed rule was made public by web posting and by public display at the Office of the Federal Register as the beginning of the comment period. They indicated that we should start the comment period only on the publication of the proposed rule in the **Federal Register** because that is where subscribers look for it. They objected to what they view as a 55-day comment period if it were to start on the date of **Federal Register** publication (August 12, 2003). Some commenters objected to the publication of the proposed rule so late in the year. They indicated that our publication on August 9 resulted in the comment period ending so close to the publication deadline for the final rule that they believed that their comments could not be fully analyzed and used and would not be as effective as if the proposed rule were published in June or early July. They urged us to publish the proposed rule in late spring. Some commenters objected to the scheduling of the APC Panel meeting so soon after the issuance of the proposed rule because they felt that it gave them inadequate time to prepare their presentations for the Panel.

*Response:* The comment period on a proposed rule begins on the day that the proposed rule is available for public comment. We believe that putting the document on display at the Office of the Federal Register and also making it available on the CMS Web site meets the test of being publicly available and that, therefore, is the start of the comment period. The publication of the proposed rule on the internet makes it available to many more people than routinely access the **Federal Register** or can visit the Office of the Federal Register where the display copy is located. The public had 60 days to comment on the proposed rule. This is the standard amount of time generally allowed for comment on notices of proposed rulemaking. Therefore, we do not believe the public was at a disadvantage or limited in the amount of time available to make public comments.

Our review of the public comments is extensive, with the comments being read and considered carefully, often by many staff. We agree that it is preferable, when possible, to issue the proposed rule as early as possible. However, the important issue is whether we have sufficient time to carefully and

thoughtfully consider all comments in development of the final rule, rather than the amount of time between the end of the comment period and the publication of the final rule.

## **II. Changes to the Ambulatory Payment Classification (APC) Groups and Relative Weights**

Under the OPPS, we pay for hospital outpatient services on a rate-per-service basis that varies according to the APC group to which the service is assigned. Each APC weight represents the median hospital cost of the services included in that APC relative to the median hospital cost of the services included in APC 0601, Mid-Level Clinic Visits. The APC weights are scaled to APC 0601 because a mid-level clinic visit is one of the most frequently performed services in the outpatient setting.

Section 1833(t)(9)(A) of the Act requires the Secretary to review the components of the OPPS not less often than annually and to revise the groups, relative payment weights, and other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act requires the Secretary, beginning in 2001, to consult with an outside panel of experts to review the APC groups and the relative payment weights.

Finally, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median (or mean cost, if elected by the Secretary) for an item or service in the group is more than 2 times greater than the lowest median cost for an item or service within the same group (referred to as the "2 times rule").

We use the median cost of the item or service in implementing this provision. The statute authorizes the Secretary to make exceptions to the 2 times rule "in unusual cases, such as low volume items and services."

For purposes of the proposed rule and this final rule we analyzed the APC groups within this statutory framework.

### *A. Recommendations of the Advisory Panel on APC Groups*

#### **1. Establishment of the Advisory Panel on APC Groups**

Section 1833(t)(9)(A) of the Social Security Act (the Act) requires that we consult with an outside panel of experts, the Panel, to review the clinical integrity of the APC groups and their