On August 24, the Centers for Medicare and Medicaid Services (CMS) issued a lengthy proposed rule (Proposed Rule) updating the hospital outpatient prospective payment system (HOPPS) under Medicare. Among other provisions, the Proposed Rule clarifies rules related to pass-through payments for medical devices and new technology APCs, including describing reductions in payments for various new technology services and detailing CMS’s formula to effectuate further reductions in pass-through payments expected to be implemented later this year.

As discussed in more detail below, the Proposed Rule sets forth the methodology CMS will use to (i) implement a pro rata reduction in pass-through payments mandated by law, and (ii) offset costs packaged into APC groups. The Proposed Rule also modifies the rules related to new technology APCs, including:

- limiting eligibility for new technology payments to complete services or procedures (not those that are part of a more comprehensive service or procedure),
- eliminating the requirement that a service have a HCPCS code,
- revising the information required to be submitted with a request to be assigned a new technology APC code, and
- offering a more flexible payment period rather than limiting payment under the new technology APC code to a minimum of two and maximum of three years.

A final rule will be published following a comment period, which will in turn include changes that will become effective on January 1, 2002. The Proposed Rule is also subject to a shortened 40-day comment period and comments must be submitted by 5 p.m. on October 3.

**Impact on Health Care Entities**

The Proposed Rule, as it relates to the pass-through payments and new technology applications, impacts primarily hospitals and drug and device manufacturers. Hospitals are directly impacted and must ensure that the payment levels expected for items and services can be cost-effective for their operations. Manufacturers, particularly medical device manufacturers, are indirectly impacted through the cost considerations of hospitals that offer existing and future products to Medicare beneficiaries. Given the potential
impact, hospitals and device manufacturers interested in commenting on the proposed rule should consult counsel for assistance in submitting comments to CMS by the October 3 deadline.

**Pass-Through Payments**

History: Federal law provides for temporary additional payments (commonly known as “transitional pass-through payments”) for certain innovative medical devices, drugs and biologicals for a minimum of two and maximum of three years. Whereas eligibility previously was product-specific, under the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), enacted on December 21, 2000, CMS was required to establish initial categories of medical devices eligible for transitional pass-through payments. CMS issued two Program Memorandums on March 22, setting forth a list of initial device categories and a means to determine a device’s initial category code based on product-specific C-codes for individual devices. CMS is also required to issue regulations delineating criteria that will be used to create additional device categories.

Application: Transitional pass-through categories are for devices only. Drugs and biologicals remain subject to existing regulations.

Pro Rata Reduction: Federal law limits the total projected amount of transitional pass-through payments each year to an “applicable percentage” of projected total payments under the hospital HOPPS (namely, 2.5 percent for years 2002 and 2003, and no more than 2 percent for 2004 and later years). If CMS estimates that the total amount of transitional pass-through payments would exceed the “applicable percentage,” a prospective uniform reduction must be instituted in that year to ensure the limit is not exceeded. CMS’s estimate is based on a database compiled by CMS from claims, cost and utilization data submitted by hospitals, manufacturers, specialty societies and other entities.

Based on information compiled by CMS so far, a significant reduction may be required in 2002. Consequently, CMS is reviewing its data and methodology and considering alternative approaches to making its estimates in an effort to minimize this likely reduction. CMS’s current methodology is based on the following assumptions and techniques:

- **Data and Methodology:** CMS will base 2002 estimates on claims used to set payment rates for 2002, pass-through amounts for drugs and radiopharmaceuticals, and device cost and use data from pass-through applications submitted by manufacturers, hospitals, specialty societies, and other entities. Estimates will be subject to price, volume and service-mix inflators (consistent with baseline HOPPS spending). Estimates for drugs, radiopharmaceuticals and devices will also be made separately and combined for the final projection.

- **Medical Devices:** CMS will make estimates by linking the frequencies for all device-related procedures in the claims data file with the cost and use data supplied by the manufacturers or other entities as part of their applications for pass-through status. Each device eligible as of January will be matched with the procedures with which it will be used. An average cost for each device or device package associated with a procedure will then be calculated. Federal law also requires that CMS calculate transitional pass-through payments for devices by adjusting the hospital’s charge for the device to cost and then subtracting an amount that reflects the device costs already included in the payment for the associated APC.

- **Drugs and Biologicals/Radiopharmaceuticals:** CMS will identify drugs/radiopharmaceuticals eligible for pass-through status that have been separately billed to Medicare on claims used for its estimate, and will multiply the frequency of use for each drug/radiopharmaceutical by its pass-through payment.

**Reductions to Offset Costs Packaged into APC Groups:**

Certain costs for prosthetic/orthotic devices, pacemakers...
and other implants were originally excluded from the APC payment rate calculation for feasibility reasons. When these costs were packaged and the APC rates recalculated, the median costs for certain procedures related to pacemakers and neurostimulators increased significantly. CMS therefore restructured the affected APCs to account for these changes in procedure level median costs.

Beginning January 1, for eligible devices, CMS deducted from transitional pass-through payments the dollar increase in the rates for the new APCs for procedures associated with the devices (and in April revised its policy to subtract such dollar amounts for each category of device). For 2002, CMS will estimate the portion of each APC rate that could reasonably be attributed to the cost of associated devices eligible for pass-through payments, and will deduct such amount from the pass-through payments. Since the deductions to the pass-through payments for costs included in APCs for 2002 are included in the recalibration of the weights and the fixed pool of dollars for outpatient services, health care entities should expect the total payment for the procedure plus devices to be reduced rather than remain constant as it did in. Deductions for 2002 range from $61 to $6,649.

**New Technology APCs**

History: CMS created a new set of technology APCs under HOPPS in a final rule issued on April 7, 2000. This final rule set forth the application process and the following five criteria used to determine whether a service is eligible for assignment to the new technology APC:

- the item or service is one that could not have been billed to the Medicare program in 1996 or, if it was available in 1996, the costs of the services could not have been adequately represented in 1996 data.
- the item or service does not qualify for an additional payment under the transitional pass-through payments.
- the item or service has a HCPCS code.
- the item or service falls within the scope of Medicare benefits.
- the item or service is determined to be reasonable and necessary under Medicare rules.

Under the April 2000 final rule, items or services meeting the new technology APC would be reimbursed for a minimum of two and maximum of three years, at which time the item or service would be moved into the existing APC structure during the annual HOPPS update. Beneficiary coinsurance for such items or services was set at 20 percent of the APC payment rate.

Proposed Modifications: Based on experience, CMS proposes in its Proposed Rule to revise the following provisions:

Definition: Eligibility for new technology APCs will be limited to complete services or procedures. This means that “items, materials, supplies, apparatuses, instruments, implements, or equipment” used to accomplish a more comprehensive service or procedure are not eligible. In addition, a service that is merely a different approach to an existing treatment or procedure will not necessarily qualify for a new technology APC (rather, costs associated with new approaches should be reflected in claims data and in annual updates to APC relative weights).

Criteria: The criteria that the service must have a HCPCS code will be eliminated and the following criteria (some of which are unchanged) will apply:

- the service is one that could not have been adequately represented in the claims data being used for the most current annual payment update (i.e., currently 1996 data).
- the service does not qualify for an additional payment under the transitional pass-through provisions.
- the service cannot reasonably be placed in an existing APC group that is appropriate in terms of clinical characteristics and resource costs.
the service falls within the scope of Medicare benefits.

the service is determined to be reasonable and necessary under Medicare rules.

Information Required: Requests for a service or procedure to be considered for assignment to a new technology APC should include:

- the name by which the service is most commonly known. Currently, only the trade/brand name is required.

- a clinical vignette describing how the service is furnished in hospitals (e.g., patient diagnoses, typical patient, resources used by the facility and physician to furnish the service). This criteria replaces the criteria for a detailed description of clinical application of the service.

- a list of any drugs or devices used as part of the service that require Food and Drug Administration approval and documentation, including date, of receipt of such approval.

- a description of where the service is currently being performed and the approximate number of patients receiving the service in each location.\(^{11}\)

- an estimate of the number of physicians who are furnishing the service nationally and the specialties they represent.

- information about the clinical use and efficacy of the service such as peer-reviewed articles.

- the CPT or HCPCS Level II codes that are currently being used to report the service and an explanation of why use of these HCPCS codes is inadequate to report the service under HOPPS.\(^{12}\)

- a list of CPT or HCPCS Level II codes for all items and procedures that are an integral part of the service (e.g., unbundled codes)

- a list of all CPT and HCPCS Level II codes that would typically be reported in addition to the service.

- a proposal for a new HCPCS code, including a descriptor and rationale for why it is appropriate, and why the item or procedure does not currently have such a code or why an existing code is inadequate.

- an itemized list of the costs incurred by a hospital to furnish the new technology service, including labor, equipment, supplies, overhead, etc.\(^{13}\)

- the name, address and telephone number of the party making the request.

- any other information required by CMS.

Payment Period: Reflecting a more flexible approach, a new service will be retained within a new technology APC group until CMS has acquired adequate data that allows it to assign the service to a clinically appropriate APC (i.e., the length of the payment period may be less than two years or more than three years\(^{14}\)).

Additional New Technology APC Groups: To pay more accurately for services, CMS proposes to split APC 0982 into two APCs—0982 for services with costs ranging from $2,500 to $3,000 and 0983 for services with costs ranging from $3,000 to $3,500. APC 0984 would then cover services with costs ranging from $3,500 to $5,000, and new APC 0985 would be added for services with costs ranging from $5,000 to $6,000.

**Drugs and Biologicals**

The Proposed Rule also clarifies that for purposes of calculating transitional pass-through payment amounts, CMS will make no distinctions between new and current drugs and biologicals. Payment status indicator “J” will be discontinued and current and new drugs eligible for pass-through payments under HOPPS will be assigned payment status indicator “G”.\(^{15}\) The Proposed Rule also proposes to update the APC rates for drugs eligible for pass-through payments in 2002 using the July or October quarterly update to the Drug Topics Red Book (which updates average wholesale prices (AWPs) for drugs) rather than the annual Red Book update (issued in April), in order to place the update on the same calendar year schedule as other annual HOPPS updates.
Conclusion

Given the shortened comment period of this Proposed Rule and its reimbursement implications, health care entities should consult counsel if interested in submitting comments to CMS regarding the pass-through, new technology APC or other provisions of the Proposed Rule.

2 Because the rule to update HOPPS payment rates must become effective by January 1, 2002, CMS found good cause to reduce the normal 60-day comment period to 40 days.
3 Section 1833(t)(6) of the Social Security Act.
5 An interim final rule with comment period will be published at a later date covering criteria for additional device categories.
7 According to CMS, these subtractions have not been made for most devices (other than pacemakers and neurostimulators), but CMS expects to begin the deductions for most other devices beginning in 2002. In the case of device packages, the deduction is made from the device package prior to multiplying that cost by the procedure frequencies. Total projected deductions are expected to reach $450 million.
8 CMS will make an appropriate adjustment for drugs not reflected in the claims data (e.g., if non-coded items are orphan drugs, they are used infrequently). CMS will also estimate expenditures for non-coded radiopharmaceuticals by using the frequency counts for all nuclear medicine procedures not billed with one of the radiopharmaceuticals.
9 The dollar amount subtracted in 2001 from transitional pass-through payments for affected categories of devices ranged from $501.27 to $2,843.00.
10 CMS will consider creating new HCPCS codes that describe the service or procedure solely for hospitals to use when billing under HOPPS.
11 This criteria and the following one provide CMS with medical contacts.
12 This criteria and the three following are refinements of the current HCPCS requirement.
13 This criteria and the two following are unchanged.
14 This two- to three-year statutory time frame is not applicable to new technology APCs, but was originally adopted by CMS for new technology APCs for consistency.
15 Essentially, CMS assumes that drugs and biologicals defined as “new” (i.e., payment was not being made prior to January 1, 1997) replace or are alternatives to drugs, biologicals or therapies whose costs would have been reflected in CMS’s 1996 claims data, that they were therefore packaged into an associated APC, and finally that the imputed acquisition cost represents that portion of the APC payment attributable to new as well as current drugs and biologicals.
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