

and proposed to modify our policy for applying offsets. Specifically, we proposed to apply an offset to a new device category only when we can determine that an APC contains costs associated with the device. We specified in the proposed rule that we would continue our existing methodology for determining the offset amount, described above. However, we solicited comments for alternative methodologies for determining the offset amounts that potentially could be applied to the payment amounts for new device categories.

We added that we could use this methodology to establish the device offset amounts for the 2004 OPSS because we are using 2002 claims on which device codes are reported. However, for the 2005 update to OPSS, we proposed to use 2003 claims that would not include device coding. Thus, for 2005, we are considering whether or not to use the charges from lines on the claim having no HCPCS code but have charges under revenue codes 272, 275, 276, 278, 279, 280, 289, and 624 as proxies for the device charges that would have been billed with HCPCS codes for these devices in previous years. We are also considering the reinstitution of the C codes for expired device categories and requiring hospitals to use one or more newly created C codes for identification of devices and costs on claims. See section VI.B of this final rule for further discussion.

We proposed to review each new device category on a case-by-case basis to determine whether device costs associated with the new category are packaged into the existing APC structure.

We reviewed the device categories eligible for continuing pass-through payment in 2004 to determine whether the costs associated with the device categories are packaged into the existing APCs. For the categories existing as of publication of the proposed rule, we determined that there are no close or identifiable costs associated with the devices in our data related to the respective APCs that are normally billed with those devices. Therefore, for these categories we proposed to set the offset to \$0 for 2004.

If we create a new device category and determine that our data contain identifiable costs associated with the devices in any APC, we would apply an offset. We proposed, if any offsets apply, for new categories, to announce the offsets in a transmittal that announces the information regarding the new category.

We received several comments on the proposal, which are summarized below along with our responses.

Comment: Device manufacturers and associations generally supported our proposal to modify our policy in applying offsets to only those device categories where we can determine that an APC contains costs associated with the device category. One commenter also recommended that we not apply offsets to those categories that do not replace current devices found in the APC costs.

Response: We will apply an offset to a new device category only when we are able to determine that an APC contains costs associated with the new device. We will also continue our existing methodology for determining any offset amount, if we find that device costs associated with a new device category are packaged into the APCs. We will include information about any applicable offset in the transmittal we issue to announce information regarding the new category.

We also will publish the device percentages related to APCs on our web site. We believe this information is useful to the public even if we do not use the information to apply any particular offset to new device categories, because we use this information to apply the tests of “not insignificant cost” to a proposed new device category application. A transitional pass-through device category must have an average cost that is not insignificant in relation to the OPD fee schedule amount, according to section 1833(t)(6)(A)(iv)(II) of the Act.

2. Multiple Procedure Reduction for Devices

In our discussion in the proposed rule of recommendations of the Advisory Panel, we noted that the Panel asked us to analyze our data to determine if we may be underpaying for devices when the multiple procedure policy is applied (68 FR 47976). We made no proposal to change our policy regarding the multiple procedure reduction for device-related APCs, but we did receive a number of comments on the topic.

Comment: Commenters stated that we should change the status indicator (SI) from “T” to “S” for APCs with packaged device costs so that the multiple procedure discount will not adversely affect the payment for APCs that contain high cost devices. One commenter indicated that no APC for which the device percentage is 50 percent or more should be subjected to a multiple procedure reduction because any such reduction would reduce the Medicare payment below the hospital’s cost for

the device. The commenter offered to work with us to develop a list of device percentages of APC payments that would not be subject to the multiple procedure reduction. Another commenter suggested that we create a modifier that could be used to override the multiple procedure reduction for certain codes with SI “T”. Some commenters said that any code that is not subject to the multiple procedure modifier under the Medicare physician fee schedule should be subjected to a multiple procedure modifier under OPSS.

Response: We are concerned that the application of the multiple procedure reduction has been a recurring theme among commenters with regard to APCs that contain significant device costs. We continue to believe that for most cases, including many cases with devices, the payment reductions for the second and subsequent payments are appropriate. This is particularly true given that there must be two procedures with SI=T for the reduction to occur. Hence, if a device procedure is performed with a non-device procedure, the non-device procedure will not be reduced if the device procedure has an SI=S, even if the non-device procedure is less costly because it was done at the same time as the device intense procedure. We are reluctant to change the SIs for device procedures because of the increase that will occur for non-device procedures. The shift in median costs will be picked up in the scaling of relative weights for budget neutrality and will result in some reduction for all services, shifting payment to procedures and away from other services types (for example, E&M, diagnostic tests).

Decisions regarding the application of the multiple procedure SIs are made independently for the Medicare physician fee schedule and the OPSS. The physician fee schedule decision is heavily dependent upon the work performed by the physician and the OPSS decision is made only with regard to the resources the hospital supplies for the service to be performed. There is no reason to believe that a decision to reduce or not reduce for multiple procedures in one system would necessarily justify that same decision in the other system.

For 2004 OPSS we have not changed the policy. However, as we did for 2003 OPSS, we have changed the SI for certain APCs for which we were convinced that the application of the multiple procedure reduction would result in inappropriate payment. For 2005, we hope to analyze the effects of a more systematic approach to determining when we should apply the