

identifier and, when used in computer systems, may yield an 11-digit number.

With the adoption of the NDC as the standard, the HCPCS codes would not be permitted to be used in a HIPAA-compliant transaction, because the NDC would be the adopted standard for reporting drugs and biologics.

There have been many discussions about the use of the NDC in professional and institutional claims since publication of the Transactions Rule. Many members of the professional and institutional sectors did not believe that the NDC should be used on their claims. The NCVHS held hearings and heard the testimony of members of the health care industry on this issue. Information provided in that testimony led us to develop the proposal to repeal the NDC as the standard for reporting drugs and biologics on all but retail pharmacy drug claims. In CMS-0003-P (67 FR 38044), we explained why the Secretary adopted the NDC and why the Secretary was proposing the repeal.

CMS-0003-P (67 FR 38044) also solicited comments on an alternative proposal to adopt an alternative standard—in place of the NDC, to be used to report drugs and biologics on non-retail pharmacy transactions. We proposed that the HCPCS code set be the alternative standard. Below we discuss comments on the proposal to repeal the NDC and the proposal to adopt an alternative standard for non-retail pharmacy transactions.

We received approximately 200 comments on this issue. The comments fell into three major categories: (1) Repeal the NDC as the standard medical data code set for professional, institutional, and dental claims and have no standard code set; (2) repeal the NDC, but adopt HCPCS as the standard code set; and (3) retain the NDC as the sole standard code set for claims from all sectors.

*Comment:* A number of commenters supported our proposal to repeal the NDC and adopt no standard in its place. These commenters, many of which were major health care industry organizations, indicated the following: (1) The current Implementation Guide usage of the NDC should remain constant and the Implementation Guide should define when the NDC would be used; (2) if no code set was selected, the Implementation Guides should not permit payers to require providers to use local code sets for drugs and biologics; (3) the cost of converting to the NDC was very high and would not justify the benefits, if any; and (4) not naming a standard would give the industry time to fully evaluate current

practices and identify preferred alternatives.

Conversely, the proposed repeal was not favored by some Medicaid State agencies, as they are required to use the NDC to report drugs and biologics to receive drug rebates.

*Response:* We agree that repealing the NDC and having no standard would be responsive to the needs of health plans and health care providers who want to evaluate further the use of NDC. The absence of a standard would permit the use of any codes as long as that use is supported by the Implementation Guide for the transaction. Repealing the NDC and having no standard would also address the concerns of many health care providers who cited the high cost and low benefit of conversion; they could continue to use HCPCS codes. Having no standard would allow many health care entities to continue their current coding practices, reducing the implementation burden, and would accommodate State agencies' requirement to report NDCs for drug rebate programs. Additionally, if there were no standard, the selection of the code set to be used would likely be specified by health plans via trading partner agreements, as long as the Implementation Guides permitted that selection.

*Comment:* The majority of commenters supported the repeal of the NDC and the adoption of HCPCS as the sole standard for reporting drugs and biologics on non-retail pharmacy transactions. Many of these commenters were institutional providers. They indicated that drug information, which is often not reported on institutional claims, is rarely used to compute payment because claims are usually paid under prospective payment systems. Since drugs are rarely reported on institutional claims, institutional health care providers would derive no benefit from the expensive transition from HCPCS codes to the NDC.

*Response:* Repealing NDC and adopting HCPCS as the standard would allay the concerns of some health care providers that more health plans might decide to implement the NDC at some point in the future. However, adopting HCPCS as the sole standard would not respond to the needs of health plans and health care providers where the specificity of the NDC is needed to compute payment or collect drug rebates.

*Comment:* Other commenters supported retaining the NDC as the standard for reporting drugs and biologics on non-retail pharmacy drug claims. Much of the support for retaining the NDC came on behalf of

State Medicaid agencies, which must use the NDC in order to receive drug rebates.

*Response:* As we have indicated, the NDC retains certain advantages over HCPCS, such as in the area of computing payments and collecting drug rebates. Additionally, the NDC enables health care providers and health plans to track effectively the utilization of drugs and access certain manufacturer information regarding the drugs. We also acknowledge that State Medicaid agencies have strongly encouraged retaining the NDC for reporting drugs and biologics on non-retail pharmacy drug claims. Retaining the NDC, therefore, as the standard would respond to the needs of health plans and health care providers who need specificity in computing payments and collecting drug rebates. It would also foster consistent drug coding for claims and among health care providers.

Simply retaining the NDC as the sole standard, however, would not adequately respond to the express concerns of those health care providers who commented that the cost of conversion to NDC would be high while the benefits would be low or non-existent. Moreover, the majority of commenters did not support keeping the NDC as the sole standard for reporting drugs and biologics for non-retail pharmacy sectors. We concluded that adopting either the NDC or the HCPCS would fail to address many of the concerns raised.

In our considerations, we recognized that both the NDC and HCPCS remain two of the most prevalent and useful code sets for reporting drugs and biologics in non-retail pharmacy transactions. The benefits of each code set complement the other's advantages very well.

We therefore decided, as we had proposed in CMS-0003-P, to repeal the adoption of the NDC for institutional and professional claims, while allowing the NDC to remain the standard medical data code set for reporting drugs and biologics for retail pharmacy claims. We believe that this decision best addresses the majority of comments received, in that for institutional and professional claims, the choice of code set will continue to be governed by trading partner agreements. However, we wish to stress that the intent of this decision is to give covered entities the full range of choices in determining which code set to use with respect to these claims, including the HCPCS and NDC codes that have been adopted as standards for other uses. Covered entities that use HCPCS should utilize the established process for requesting new codes, rather