

than supplementing the code sets with locally developed codes.

The result of this repeal will be that there is no identified standard medical data code set in place for reporting drugs and biologics on non-retail pharmacy transactions. The absence of a code set would not preclude the use of NDC for reporting drugs and biologics by covered entities on standard transactions. Covered entities could continue to report drugs and biologics as they prefer and agree upon with their trading partners.

Comments from the different parts of the industry demonstrated that no one code set is able to meet the different needs now addressed by the NDC and HCPCS. Adopting no standard at this point will allow for innovation, and permit development of new coding systems that meet the full range of business needs. Comments also indicated that the costs for a hospital or other institution to comply with the NDC for reporting drugs and biologics on institutional claims could exceed its costs for adopting all other HIPAA transaction standards. For many health care providers, entire claim systems would need to be replaced, re-engineered, or both.

We also considered the concerns expressed by the NUBC regarding the use of the NDC on institutional claims, including hospital claims. NUBC has indicated that reporting specific drugs on institutional claims introduces a systems technology requirement that is inconsistent with inpatient claims submission and institutional provider reimbursement, which are typically based on a Diagnosis-Related Group or per diem payment methodology. The NUBC has also expressed its belief that the NDC coding system is more suited for inventory control and is not appropriate for institutional provider billing, and further that the NDC pertains to retail pharmacy claims only and should not be applicable to institutional claims.

We are also aware that retaining the NDC as the sole standard for institutional claims would pose significant operational issues on institutional pharmacies because of systems incompatibility among the pharmacies, inpatient medical records, and inpatient accounting systems. Physicians generally order drugs for patients through the hospital pharmacy department by name, unit, and dosage frequency. The pharmacy department however does not reference the NDC to initiate the charge transaction. Additionally, the NDC formats do not provide information related to actual dosages administered, or provide a

methodology for multiple billing increments. Attempts by the industry to develop a complete crosswalk from the current HCPCS codes to the NDC have been unsuccessful.

Another important factor in our decision, as we mentioned in CMS-0003-P, was the information we received from the Subcommittee on Standards and Security of the NCVHS as a result of the public hearings it held on February 1, 2001, regarding HIPAA implementation issues and the NDC. In addition to the problems we identified above, concerns expressed during that meeting included the burden of training additional ancillary staff to use the NDC and the potential for increases in medical errors when new system interfaces for drug dispensing systems are created.

The NCVHS in a February 22, 2001, letter to the Secretary recommended that the Secretary repeal the adoption of the NDC as the standard medical data code set for reporting drugs and biologics in standard transactions other than retail pharmacy transactions. It also suggested that HCPCS codes as well as the NDC continue to be used in the standard institutional and professional claim transactions. Moreover, the NCVHS explained that it believes that no drug coding system in existence today meets all the needs of the health care industry. A future coding system that could be used effectively and efficiently for drug inventory, pharmacy transactions, patient care, billing arenas, and ensuring patient safety would be the best answer to this problem, according to the NCVHS.

We note therefore that another significant advantage to repealing the adoption of the NDC for reporting drugs and biologics in non-retail pharmacy standard transactions and not adopting a replacement standard code set at this time is that the industry and HHS will have time to explore the development of a new drug coding system to meet current and future needs of this sector of the health care industry. We would note that the Implementation Guides for institutional and professional claim transactions currently recognize the use of only the NDC and HCPCS codes for drugs and biologics. See the discussion at section G.2 below. The developer of a new code set could request that it be included in the guides via the DSMO maintenance process.

Thus, based on comments received and our own review of the available code sets, we believe that our decision to repeal the adoption of the NDC as the standard medical data code set for reporting drugs and biologics in all non-retail pharmacy transactions is the best

and most appropriate decision at this time. Repealing the NDC as the standard medical code set for reporting drugs and biologics in non-retail pharmacy transactions also raises opportunities for the development of a more robust drug coding system that overcomes the deficiencies inherent in the NDC and HCPCS codes for reporting drugs and biologics on standard transactions. For example, because of the inadequacy of existing codes for drug products, and the need for harmonization of medical terminology, the FDA has been working with the National Library of Medicine and the Department of Veterans Affairs to develop improved drug codes.

In preparing this final rule, we consulted with the FDA and noted that the FDA is preparing two new regulations that relate to the use of the NDC number that will be proposed for public comment soon. Both proposed rules will propose changes related to coordinating the NDC with bar coding. It is expected that the proposed changes will make the NDC number more useful to those who choose to use the NDC.

5. Retail Pharmacy Drug Claims

The Transactions Rule adopted the NCPDP transaction as the standard for retail pharmacy drug claims (§ 162.1102(a)), and the ASC X12N 837—Professional Health Care Claim as the standard for professional services (§ 162.1102(c)). Neither of our May 31, 2002, proposed rules solicited comments on the formats to be used by retail pharmacies when submitting claims for drugs, supplies, durable medical equipment, prosthetics, orthotics, and professional services.

The DSMOs are currently discussing this item in their consideration of two pending change requests that were introduced into the DSMO process within the past year. (These requests were not submitted in time to be considered under the “fast track” approach described in this final rule in section I. C., “Designated Standard Maintenance Organization (DSMO) Process.”)

In submitting comments on issues presented in our two May 31, 2002, proposed rules, some commenters included comments on the formats for retail pharmacy drug claims for items and services other than drugs. Such items included syringes, which are supplies that are usually purchased with drugs such as insulin. Services included consultations with patients and the administration of vaccines (such as the influenza vaccine) to individuals. The issue of the format on which retail pharmacy supply claims should be billed is tied closely to business