

Response: After considerable discussion and evaluation of current industry practices, we determined that this information is available, but not currently required, on institutional claims. The implementation specifications adopted by the Transactions Rule established the usage of line level provider information as required when the provider information at the line level was different from that at the claim level. The Addenda for the implementation specifications modify the usage of line level provider information from required to situational. The specific situation when this information would be required is when line level provider information is known to impact claim adjudication.

Comment: A few commenters noted that a usage change instruction for Operating Physician Specialty Information points to an incorrect segment.

Response: We agree with this comment. ASC X12N has made the appropriate corrections and added this modification to the Addenda adopted by this final rule.

2. Transaction Standard for Health Care Claims or Equivalent Encounter Information: Professional

Comment: Several commenters stated that the implementation specification requirement proposed for the use of the NDC conflicted with the proposed regulation text for CMS-0003-P (67 FR 38044). In our CMS-0003-P proposed rule, we proposed repealing the NDC for reporting drugs and biologics on non-retail pharmacy transactions and that no standard for reporting drugs and biologics on non-retail pharmacy transactions be adopted at this time. CMS-0005-P (67 FR 38050) proposed adoption of the Addenda that required usage of the NDC information when necessary to add definition to a particular product. One commenter suggested that this be clarified by adding a mutually defined "ZZ" qualifier to permit usage of any code sets based on trading partner agreements.

Response: This final rule adopts the modified Addenda approved by ASC X12N in October 2002. The Addenda permit use of either the NDC or HCPCS to code drugs and biologics on non-retail pharmacy claims, but (with limited exceptions) do not permit other codes to be used for this purpose. However, this choice of either HCPCS or NDC codes is not consistent with our decision, reflected in § 162.1002(c) below, to repeal the standard code set for drugs and biologics for non-retail pharmacy transactions and to permit the use of all code sets in order to encourage development of a single code set that

will meet the needs of the entire health care industry. We expect that the choice of either the HCPCS or the NDC codes afforded by the Addenda will, in the usual case, result in covered entities in the non-retail pharmacy sectors of the industry continuing to code drugs and biologics as they do now, whether by NDC or by HCPCS. The Addenda will thus not create a disincentive for industry to develop, and migrate to, a single code set for use by the industry.

Although we agree that in this respect the Addenda are not consistent with our underlying policy choice regarding the code sets for drugs and biologics for non-retail pharmacy transactions, the adopted Addenda contain many important changes to the Implementation Guides that are essential if industry is to be able to test and implement the transactions in question smoothly and on time. Because we cannot, under the statute, choose among provisions in an industry-adopted standard guide without going through negotiated rule making, the critical need for the remainder of the changes in the Addenda has led us to adopt the Addenda in their present form. We intend, however, to work with industry to align the Addenda with the policy reflected at § 162.1002(c) and adopt a further modification of the standards to effect this alignment in the next update. Should we not be able to reach agreement on the inconsistency between our policy decision and the policy reflected in the Implementation Guides, we intend to pursue our options under the statute that include negotiated rule making. We recognize that the existence of what is, in effect, two standards for coding drugs and biologics within the transactions in question may cause problems between health plans and health care providers and may in some cases result in noncompliance. It is unlikely that we would pursue any such instances of noncompliance, in light of the competing demands for enforcement resources and the inconsistency between our policy decision and the policy reflected in the Implementation Guide.

With respect to the comment about ZZ codes, the adopted Addenda only permit use of ZZ qualifiers for certain situations. Thus, the problem discussed above likewise exists with respect to such codes, and we adopt the same approach thereto.

Comment: One commenter listed three modifications that had been approved by the DSMOs but were not included in the Addenda specifications. These modifications related to Initial Treatment Date, Spinal Manipulation Certifications for Medicare Part B, and the Test Date for Dialysis Patients.

Response: We verified that these modifications were adopted in the proposed Addenda but due to typographical errors were inadvertently not included in the proposed Addenda. ASC X12N has corrected these errors and added these modifications to the Addenda adopted by this final rule.

Comment: We received many comments from anesthesiology providers requesting that we not adopt the proposed usage instruction that allows reporting anesthesia services in minutes only. Current business practices require that reimbursement for anesthesia services be based on total anesthesia time in minutes or units. Adopting this proposed usage instruction in the Addenda would impact reimbursement methodologies and payment amounts for anesthesia providers.

A number of commenters requested HHS to adopt a standard definition for anesthesia time. A generally accepted definition for most payers, including Medicare, that is consistent with the American Society of Anesthesiologists' definition, defines anesthesia time as starting when the practitioner begins to prepare the patient for anesthesia services and ending when anesthesia services are no longer being provided and the patient is safely in postoperative care. However, a minority of payers account for anesthesia time differently, requiring multiple reporting for face-to-face start and stop times, if there are different clinical activities in a particular service. A commenter pointed out that the sporadic need to depart from a widely accepted methodology is burdensome and results in frequent reporting errors.

Response: We agree with the comment to delete the usage instruction requiring the reporting of minutes only for anesthesia services. Based upon various payment systems for anesthesia services that depend upon reporting unit information on claims, and the various methods for calculating one unit of time, we determined that adopting a standard requiring that only minutes be reported would impact anesthesia providers' ability to report their services adequately. Regarding the request for a standard definition for anesthesia time, we believe that the applicable comments actually seek further clarification of health plans' reimbursement policies, which are not the subject of these transaction standards.

Comment: Several commenters objected to a modification of the requirement for spinal and non-spinal manipulation service information. This