

vaccinations covered by the Medicare Program (In order to promote an increase in the flu vaccinations for Medicare beneficiaries, since 1993 Medicare allowed mass immunizers to bill the program using a single claim form with an attached list of beneficiaries to which a flu vaccine was administered. Generally, mass immunizers bill electronically, but in a non-standard format. This roster billing simplified provider billing but is not available in electronic form under the HIPAA Transaction Rule); (2) claims for payment under Medicare demonstration projects (Medicare demonstration projects often allow for unusual situations not normally handled by the standard transactions.); and (3) claims where more than one plan is responsible for payment prior to Medicare. The standard electronic formats do not currently have a clear method for the reporting of per service payments made by more than one primary payer. Efforts are being made to resolve this deficiency. These claims can continue to be submitted to Medicare on paper, but once a solution is reached we will notify the public, and providers will then be required to submit these claims electronically. Specific program guidance will be issued to Medicare providers concerning submission of these claims on paper effective October 16, 2003. We will also issue specific guidance or regulations, as necessary, informing covered entities if this or another exception no longer applies. (b) In 424.32(d)(3)(ii), we provide that electronic submission will be waived when the entity submitting the claim is a small provider or small supplier. The statute is quite specific as to the size requirements and the rule simply incorporates the statutory requirements.

#### *D. Unusual Circumstances*

The Secretary may waive the electronic submission requirement in certain situations as the Secretary finds appropriate. In § 424.32(d)(4), we specify three circumstances that will provide for an exception to exist in the following situations: (1) The submission of dental claims (This exception is being included because, under HIPAA, dentists are required to submit electronic transactions to other payers in a format different from that generally used in the Medicare Program. Since Medicare does not generally cover dental services, this exception is added to minimize the burden on dentists who may, at times, need to bill the Program.); (2) A service interruption in the mode of submitting the electronic claim that is outside of the control of the entity submitting the claim, for the period of

the interruption (This exception will apply only if the physician, practitioner, facility, supplier, or other health care provider has no telephone or other communication service. If telephone service exists but is unavailable for a period of time (for example, because of inclement weather or due to telephone company technical breakdowns), paper claims will be accepted during the period of disrupted telephone service.); and (3) On demonstration, satisfactory to the Secretary, of other extraordinary circumstances precluding submission of electronic claims.

Entities will not generally need to make a special request to determine whether an exception applies that would make them eligible for a mandatory waiver under § 424.32(d)(3) or a discretionary waiver under § 424.32(d)(4). A special request must be submitted to a Medicare FI or carrier when an entity does not meet the mandated or discretionary waiver criteria being established but believes there are other extraordinary circumstances that preclude their submission of electronic claims. We will issue program guidance to Medicare FIs and carriers to enable them to handle, on a case-by-case basis, requests for relief in extraordinary circumstances.

#### *E. Enforcement*

ASCA's amendment to section 1862(a) of the Act prescribes that "no payment may be made under Part A or Part B of the Medicare Program for any expenses incurred for items or services" for which a claim is submitted in a non-electronic form. Consequently, absent an applicable exception, paper claims submitted to Medicare will not be paid.

The Secretary may audit entities that bill Medicare non-electronically. Entities determined to be in violation of the statute or this rule may be subject to claim denials, overpayment recoveries, and applicable interest on overpayments.

#### *F. Effective Date*

In § 424.32(d)(6), we specify the effective date for these amendments will be for claims submitted on or after October 16, 2003. This effective date is specified in section 3(b) of ASCA.

### **III. Response to Comments**

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, if we revise this

final rule, we will respond to the major comments in the preamble to that document.

### **IV. Waiver of Proposed Rulemaking**

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority, under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We find that it would be contrary to the public interest to undertake prior notice and comment procedures before implementing this interim final rule with comment period. The ASCA evidences the Congress' intent to increase electronic claims submission to the Medicare Program through mandatory electronic billing requirements and to tie the mandatory Medicare electronic billing requirement's October 16, 2003 effective date to the compliance date for national implementation of the electronic transactions standards required under the Administrative Simplification provisions of HIPAA (see 45 CFR parts 160 and 162). However, the ASCA also provides that not all Medicare health care providers must engage in electronic billing and identifies, in general terms, those circumstances under which health care providers will be exempt from the requirements.

The implementation of the HIPAA standards by health care providers requires detailed planning, budgeting, implementation, and testing in order for those covered entities to be ready to submit HIPAA transactions by the October 16, 2003 compliance date. Since section 3 of ASCA mandates electronic billing for Medicare providers, these entities must come into compliance with the HIPAA requirements on the same date and, in turn, they must plan appropriately like those covered entities that were already planning to be electronic billers. It is imperative that the affected Medicare billers have sufficient time to ascertain whether they must transition to electronic billing as a result of section 3 of ASCA and, if so, begin the implementation process for the HIPAA transaction standards. This interim final rule with comment period allows those