C. Petitions for Judicial Review

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this approval of an alternative set of final ASM test cutpoints to Pennsylvania's I/M program SIP must be filed in the United States Court of Appeals for the appropriate circuit by October 14, 2003. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: August 6, 2003.

Donald S. Welsh,

Regional Administrator, Region III.

■ 40 CFR part 52 is amended as follows:

PART 52—[AMENDED]

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart NN—Pennsylvania

■ 2. Section 52.2020 is amended by adding paragraph (c)(211) to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(211) Revisions to the Pennsylvania Emission Inspection Program Regulations to adopt revised alternative final ASM test cutpoints submitted on July 23, 2003 by the Department of Environmental Protection:

(i) Incorporation by reference.

(A) Letter of July 23, 2003 from the Secretary of the Department of Environmental Protection transmitting a regulatory amendment to the motor vehicle emissions testing program to adopt an alternative set of final ASM test cutpoints developed by EPA.

(B) Revisions to Chapter 177, Appendix A, Section 1 of the Pennsylvania motor vehicle emission inspection program regulations (codified in the Pennsylvania Code at Title 67, Part I, Subpart A, Article VII), effective on May 24, 2003.

(ii) Additional Material.—Remainder of the State submittal pertaining to the revisions listed in paragraph (c)(211)(i) of this section.

[FR Doc. 03–20895 Filed 8–14–03; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS–0008–IFC]

RIN 0938–AM22

Medicare Program; Electronic Submission of Medicare Claims

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period implements the statutory requirement that claims for reimbursement under the Medicare Program be submitted electronically as of October 16, 2003,except where waived. This rule identifies those circumstances for which mandatory submission of electronic claims to the Medicare Program is waived.

DATES: *Effective date:* October 16, 2003. These regulations are applicable for Medicare claims submitted on or after October 16, 2003.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 14, 2003.

ADDRESSES: In commenting, please refer to file code CMS–0008–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission or e-mail. Mail written comments (one original and three copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–0008–IFC, P.O. Box 8010, Baltimore, MD 21244–8010.

Please allow sufficient time for mailed comments to be timely received in the event of delivery delays. If you prefer, you may deliver (by hand or courier) your written comments (one original and three copies) to one of the following addresses: Room 445–G, Hubert H. Humphrey (HHH) Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–8010.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for commenters wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed, and could be considered untimely.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Kathleen Simmons, (410) 786–6157. Stewart Streimer, (410) 786–9318.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, contact Sharon Jones (410) 786–9994.

Copies: Additional copies of the **Federal Register** containing this interim final rule with comment period can be made at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

This **Federal Register** document is also available from the **Federal Register** online database through *GPO Access,* a service of the U.S. Government Printing Office. The Web site address is: *http://www.access.gpo.gov/nara/index.html.*

I. Background

Section 3 of the Administrative Simplification Compliance Act (ASCA), Pub. L. 107–105, was enacted by the Congress to improve the administration of the Medicare Program by facilitating program efficiencies gained through the electronic submission of Medicare claims. Section 3 of ASCA amends subsection (a) of section 1862 of the Social Security Act (the Act) (42 U.S.C. 1395y(a)) and adds a new subsection (h) to section 1862 (42 U.S.C. 1395y). The amendment to subsection (a) requires

the Medicare Program, subject to subsection (h), to deny payment under Part A or Part B for services ''for which a claim is submitted other than in an electronic form specified by the Secretary.'' Subsection (h) provides that the Secretary shall waive such denial in two types of cases and may also waive such denial ''in such unusual cases as the Secretary finds appropriate.''

Section 3 of ASCA operates in the context of the Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191. Those provisions require the Secretary to adopt, among other standards, standards for financial and administrative transactions for the health care industry, including the health care claim transaction (see section 1173(a) of the Act). In 2000, the Secretary of Health and Human Services (HHS) adopted standards for eight electronic transactions, including the Health Care Claim or Equivalent Encounter Information transaction, 65 FR 50312 (August 17, 2000). These rules, which are codified at 45 CFR part 162, subparts A and I through R, are generally known as the Transactions Rule.

The HIPAA standards apply to health plans, health care clearinghouses, and certain health care providers; collectively, these entities are known as ''covered entities.'' Covered entities are required to comply not only with the Transactions Rule, but also with the other HIPAA Administrative Simplification rules—the Privacy Rule, the Employer Identifier Rule, and the Security Rule—when the respective applicable compliance dates for those rules occur.

Compliance with the standards for the electronic transactions covered by the Transactions Rule was required for all covered entities other than small health plans by October 16, 2002; compliance by small health plans is required by October 16, 2003. However, section 2 of ASCA extended the October 16, 2002 compliance deadline to October 16, 2003 for covered entities that submitted a compliance plan by October 15, 2002. Covered entities that were not small health plans and that did not timely submit a compliance plan under ASCA were required to comply with the Transactions Rule by October 16, 2002. Regardless, no later than October 16, 2003, all covered entities must be in compliance with the Transactions Rule.

By statute, the Medicare Program is a health plan under HIPAA (see section 1171(5)(D) of the Act). It is, therefore, a covered entity. Health care providers are covered entities if they transmit health information in electronic form in connection with a transaction for which the Secretary has adopted a standard (covered transaction) (see 45 CFR 160.102). Under the Transactions Rule, if a covered entity electronically conducts a covered transaction with another covered entity, it must conduct it as a standard transaction (see 45 CFR 162.923(a)).

Approximately 86.1 percent of claims submitted to the Medicare Program are submitted electronically, which means that approximately 139 million claims are submitted on paper per year (fiscal year (FY) 2002). Section 3 of ASCA requires Medicare providers to submit claims electronically by October 16, 2003, unless one of the specified grounds for waiver applies. Section 3 of ASCA, thus, in general has the effect of requiring Medicare providers that are not already covered entities to conduct a covered transaction (the health care claim transaction) electronically and, thereby, become covered entities. In submitting claims electronically, the providers will be required to comply with the applicable HIPAA standard for the health care claim transaction, by virtue of the Transactions Rule. Thus, section 3 of ASCA promotes the submission of standard transactions and will further the goal of improved health care delivery by reducing the administrative burden and paperwork associated with Medicare claims submission.

Although 86.1 percent of Medicare claims are submitted electronically, the volume of Medicare claims submitted in paper form is substantial, and moving from paper to electronic submission has the potential for significant savings and efficiencies for Medicare physicians, practitioners, facilities, suppliers, and other health care providers, as well as for the Medicare program itself. Although these Medicare physicians, practitioners, facilities, suppliers, and other health care providers would incur a cost to comply with the mandatory electronic billing requirement, we believe their savings will offset the cost. Further, the use of the HIPAA electronic claim standard could result in additional savings should these entities begin electronically billing other payers. However, the statute recognizes that certain circumstances may preclude or make less attractive converting from a paper to an electronic environment. ASCA, thus, identifies exceptions to the mandatory submission of electronic Medicare claims. These exceptions are interpreted and provided for by this interim final rule with comment period.

We considered whether the amendment to section 1862(a) in section 3 of ASCA could be interpreted to apply to payments made by Medicare + Choice (M+C) organizations to providers for services provided to Medicare beneficiaries. The question was raised by the provision in section 4 of ASCA which expressly adds Medicare Part C, found in Part C of Title XVIII, to the definition of Medicare ''health plans'' found in section 1171(5)(D).

The plain language of section 1862(a), however, provides that ''payment may not be made under Part A or Part B'' for a number of activities. The Congress could have amended this provision, just as it amended section 1171(5), if it had wanted to prohibit M+C organizations from paying for claims for services given to M+C enrollees by the M+C organization's participating providers. The fact that it did not so amend this provision indicates that it did not intend to apply the ASCA payment prohibition to the M+C organizations. The Congress's intent to apply the broader definition of ''health plan'' in section 4 of ASCA solely to the Administrative Simplifications provisions of HIPAA and not to the electronic submission requirement for Medicare claims is further suggested by in the title of section 4 of ASCA: ''Clarification with Respect to Applicability of Administrative Simplification Requirement to M+C Organizations.''

The M+C organizations, as health plans for the purposes of HIPAA Administrative Simplification, are required to come into compliance with the requirements of the HIPAA Transactions Rule no later than October 16, 2003. We understand that all M+C organizations properly filed ASCA compliance plans prior to October 16, 2002. They, therefore, obtained extensions and have a compliance date of October 16, 2003.

An M+C organization that pays a non-compliant electronic claim after October 16, 2003, would accordingly be out of compliance with the HIPAA Transactions Rule requirements, but would not violate the provisions of section 1862(a)(22) or the requirements of this regulation. This regulation applies only to providers, practitioners and suppliers who submit claims under Part A or Part B of Medicare. It does not apply to the submission of claims by providers to M+C organizations. Moreover, the waiver provisions for small providers, practitioners and suppliers established by section 3 of ASCA and this regulation do not extend to claims submitted by such providers to any health plans other than Medicare.

II. Provisions of the Interim Final Rule With Comment Period

Section 3 of ASCA established the requirements and exceptions under the Medicare Program for the mandatory submission of claims submitted in electronic form. 45 CFR 162.1101(a) defines a health care claim as the transmission of ''A request to obtain payment, and the necessary accompanying information from a health care provider to a health plan, for health care.'' 45 CFR 160.103 defines electronic media as—

(1) Electronic storage media including memory devices in computers (hard drives) and any such removable/transportable digital memory medium, such as magnetic tape or disk, optical disk, or digital memory card; or (2) Transmission media used to exchange information already in electronic storage media. Transmission media include, for example, the internet (wide-open), extranet (using internet technology to l ink a business with information accessible only to collaborating parties), leased lines, dial-up lines, private networks, and the physical movement of removable/transportable electronic storage media. Certain transmissions, including of paper, via facsimile, and of voice, via telephone, are not considered to be transmissions via electronic media, because the information being exchanged did not exist in electronic form before the transmission.

In this interim final Rule with comment period, we integrate the definitions of ''electronic media'' and ''claims submitted in electronic form'' into the newly defined term, ''electronic claim.'' Furthermore, for brevity, and to reflect common use, the term ''electronic claim(s)'' is considered to be synonymous with and is being used in lieu of the term ''claims submitted in electronic form'' in this Rule.

A. Definitions Used for Electronic Claim Submission

In § 424.32(d)(1), we are adding a definition section to define terms used in paragraph (d). We define the following terms: claim; electronic claim; direct data entry; electronic media; initial Medicare claim; physician, practitioner, facility or supplier; provider of services; and small provider or small supplier. We define ''claim'' to mean the transaction defined at 45 CFR 162.1101(a), which is the regulatory definition of ''health care claim'' in the Transactions Rule. We specify the definition of ''electronic claim'' to mean a claim that is submitted via electronic media. We specify that the definitions of ''direct data entry'' and ''electronic media'' are defined as those terms are defined in 45 CFR 162.103, and 160.103, respectively.

In § 424.32(d)(1)(iv), we define an ''initial Medicare claim'' as a claim submitted to Medicare for payment under Part A or Part B of the Medicare Program for the first time for processing, including claims sent to Medicare for the first time for secondary payment purposes. *Initial Medicare claim* excludes any adjustment or appeal of a previously submitted claim.

We specify in § 424.32(d)(1)(vi) that a ''Physician, practitioner, facility, or supplier'' is a Medicare provider other than a *provider of services.* In § 424.32(d)(1)(vii), we define a ''Provider of services'' as a provider of services as defined in section 1861(u) of the Act. We define in § 424.32(d)(1)(viii), a ''Small provider or small supplier'' as a provider of services with fewer than 25 full-time equivalent employees; or a physician, practitioner, facility, or supplier (other than provider of services) with fewer than 10 full-time equivalent employees.

B. Submission of Electronic Claims Required

Electronic submission of Medicare claims is required for *initial* Medicare claims, including initial claims with paper attachments, submitted for processing by the Medicare fiscal intermediary (FI) or carrier that serves the physician, practitioner, facility, supplier, or other health care provider. No other transactions, including changes, adjustments, or appeals to the initial claim, are required to be submitted electronically.

In § 424.32(d)(2), we specify that except for claims to which § 424.32(d)(3) applies, an initial Medicare claim under Part A and/or Part B may be paid only if submitted as an electronic claim for processing by the Medicare FI or carrier that serves the physician, practitioner, facility, supplier, or provider of services. This requirement does not apply to any other transactions, including adjustment or appeal of the initial Medicare claim.

C. Exceptions to Requirement To Submit Electronic Claims

The regulation set forth at 45 CFR 162.923 states that ''Except as otherwise provided in this part, if a covered entity conducts with another covered entity (or within the same covered entity), using electronic media, a transaction for which the Secretary has adopted a standard under this part, the covered entity must conduct the transaction as a standard transaction.'' HIPAA does not require that a health care plan be able to accept claims via every type of electronic media, only that claims received via such media comply with the standard format and content requirements of HIPAA *(www.wpc-edi.com/HIPAA).* Only electronic media accepted by Medicare, and as defined in the Medicare Carrier and Intermediary Manuals and Program Memoranda issued by CMS, are affected by this requirement of ASCA. At present, Medicare does not accept claims via the internet, an extranet or, in many cases, via removable/transportable storage media. This rule does not change this Medicare policy. Advance notice of any future plans for expansion or contraction in the electronic media accepted for submission of Medicare claims would be published in Medicare program instructions and via routine contractor notification and instructional media.

Claims submitted via a direct data entry screen maintained for Medicare, and as permitted by 45 CFR 162.923, are considered to be electronic claims for purposes of this requirement. Claims transmitted to a Medicare contractor using the free or low cost claims software issued by Medicare fee-for-service plans are also electronic claims for purposes of this requirement.

The ASCA provides for exceptions to the mandatory electronic submission of Medicare claims. Under the ASCA, the Secretary of Health and Human Services will waive the application of the electronic claim requirement for specific cases. This interim final rule with comment period provides more explicit requirements to implement the statutory mandate that we specify in the regulations at § 424.32(d). Specifically, in § 424.32(d)(3), we specify the exceptions when electronic submission of initial Medicare claims can be waived. In § 424.32(d)(3)(i), we specify that electronic submission will be waived when: (a) there is no method available for the submission of an electronic claim. We cannot reasonably expect Medicare beneficiaries to submit electronic claims. (Even though, the statute requires, with very few exceptions, that providers of health care bill Medicare on behalf of a beneficiary (sections 1814(a) and 1848(g)(4) of the Act) some beneficiaries will still submit claims to Medicare. However, those relatively few beneficiaries who submit claims are not likely to possess the capability to submit a HIPAA compliant claim). Further, there is no method available in those situations in which the standard adopted by the Secretary at 45 CFR 162.1102 does not support all of the information necessary for payment of the claim. At this time, we have identified three situations which fall into this category, in addition to beneficiary claims: (1) Roster billing of

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 whether 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

Medicare paper billers to fully understand their obligations under ASCA and, in turn, begin preparing for HIPAA implementation, if required to do so. We believe any delay in implementing this rule, effective October 16, 2003, would hinder Medicare providers' ability to meet the October 16, 2003 HIPAA compliance date or determine that they did not have to file electronically with Medicare and so incur unnecessary costs.

Thus, we find, for good cause, that providing notice and opportunity to comment under 5 U.S.C. 553(b) would be impracticable and contrary to the public interest. We are providing a 60-day public comment period.

This rule is effective October 16, 2003, as required by section 3(b) of the ASCA.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

The information collection requirements and associated burdens in § 424.32 are subject to the PRA. The burden of submitting the information required is addressed under OMB approval number:

0938–0866, HIPAA Standards for Coding Electronic Transactions, with a one-time burden of 34,000,000 hours. The current approval expires 5/31/05.

0938–0279, Medicare Uniform Institutional Provider Bill, with an annual burden of 1,666,208 (form CMS–1450). The current approval expires 12/31/05.

0938–0042, Request for Medicare Payment—Ambulance, with an annual burden of 390,418 hours (form CMS–1491). The current approval expires 3/31/04.

0938–0008, Common Claim form, instructions, and supporting regulations at §§ 414.40, 424.32, and 414.40, with an annual burden of 44,189,007 (form CMS–1500). The current approval expires 3/31/06.

Approximately 205,409 providers and suppliers will be affected by this rule and will have to change the format for the claims they submit (the information collected does not change). They will incur some costs, either that of switching to clearinghouses, which will not affect the time it takes to submit the information for a claim, but will cost them $.30 per claim, or that of purchasing computer equipment, which we estimate at $500 to $1,000.

For our rule published to implement the electronic transactions in general, we estimated that it would take an average of ten hours per entity to switch over to the mandated standard transaction. (The switch could be from paper to electronic or from another electronic format to the standard format.)

For purposes of this discussion, we are estimating that 37.5 percent of the affected providers and suppliers (that is, those not meeting one of the exceptions) already own computers and will not incur capital costs. We are also estimating that 50 percent of the affected providers and suppliers will start using a clearinghouse or billing service, which will not impose any capital costs subject to the PRA. The remaining 12.5 percent (25,676) will buy computers at an average of $750, for a total capital cost of $19.3 million.

On the other hand, the providers and suppliers who own or who will buy a computer will require less time to submit claims. Form CMS–1450 takes approximately 9 minutes to submit in hard copy and .5 minutes to submit electronically; form CMS–1500 takes 15 minutes and 1 minute, respectively; form CMS–1491 takes 10 minutes and 1 minute, respectively.

If the 50 percent of the entities that will bill us directly are responsible for 25 percent of the paper bills (we assume that half of the bills are submitted by entities that will be excepted from the requirements, and that 25 percent will be submitted through an intermediate party), they will save 7,651,089 million hours for form 1500, 58,850 hours for form 1491, and 129,196 hours for form 1450. Mailing costs will be reduced by approximately $.40 per claim on average and the cost of the forms by $.03 for the form 1450 and form 1500 (the third form is furnished by CMS). We welcome comments on this aspect of the collection.

We are submitting a copy of the revision to § 424.32 to OMB for its review of the information collection requirements. The revision is not effective until OMB has approved it. If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following: Office of Strategic Operations and Regulatory Affairs, Centers for Medicare and Medicaid Services, 7500 Security Boulevard, Attn: PRA Reports Clearance Officer, Baltimore, MD 21244, Attn: Julie Brown, CMS–0008–IFC, and Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, Desk Officer, CMS–0008–IFC.

VI. Regulatory Impact Analysis

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

For the purpose of this analysis, CMS uses a pre-statute baseline; therefore, all costs and benefits identified in this impact analysis are attributed to this rulemaking. Nevertheless, the ASCA mandates most aspects of this rulemaking. In particular, the ASCA requires Medicare providers to submit claims electronically and stipulates exceptions that will and may be granted. However, CMS did have discretion in setting the conditions for exceptions, and believes that these exceptions reduce the burden relative to the burden that may have been imposed by ASCA without this enabling regulation.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). This is not a major rule. While additional costs will be imposed on those entities that do not meet any of the exception requirements and which must purchase the capability to

bill Medicare electronically, we estimate the impact to be less than $100 million. Our estimates of the cost impact are based on the following analysis. (**Note:** The primary sources of data contained herein are the Medicare Program's ''Contractor Reporting of Operational Workload Data'' (CROWD), the ''2002 CMS Statistics'' Handbook), and the Year 2000 ''Statistics of U.S. Business'' issued by the U.S. Census Bureau.

The Administrative Simplification provisions under HIPAA establish the standards for electronic data transmission when transactions are conducted electronically, but they do not require physicians, practitioners, facilities, suppliers, and other health care providers to transmit claims and other transactions electronically. ASCA, however, does require Medicare physicians, practitioners, facilities, suppliers, and other health care providers (except those for which this rule provides for an exception) to submit claims electronically to Medicare. Consequently, Medicare claims must be submitted in the HIPAA-prescribed electronic format. Thus, this rule will only have an impact on that group of entities that now submit paper claims to the Medicare Program and who do not fall into one of the excepted groups.

Approximately 139 million paper claims were submitted to Medicare in FY 2002. This represents about 13.9 percent of all claims processed. Broken down between paper claims submitted to FIs and carriers, the number of paper claims in FY 2002 was 3.4 million and 136 million, respectively (source of data is CROWD).

Over the past 4 years, Medicare's electronic media claims rate (EMC) has slowly grown at an average of 0.3 percent per year for FIs and 0.9 percent per year for carriers (source of data is CROWD). We do not expect a change in this trend for the immediate future. Therefore, we assume that similar changes will continue for, at least, FY 2003 and FY 2004, the first year of implementation of mandatory Medicare EMC. Using workload growth projections from the CMS FY 2004 budget submission to the Congress, we estimate the FY 2004 volume of paper claims impacted by the ASCA, factoring out Medicare's continuing trend of higher EMC rates, will be 2.5 million for Medicare FIs and 133.7 million for carriers. Please note that these volumes could be even smaller in FY 2004 due to the simultaneous implementation of HIPAA. However, the impact of HIPAA, coupled with Medicare's EMC trends, cannot be quantified, though the impact would only further reduce the cost/savings impact of ASCA and further support that a RIA is not needed.

We do not know at this time how many providers will be excepted from the ASCA requirements, but projections have been made based upon the percentage of health care providers reported in the Census Bureau's ''Year 2000 Statistics of U.S. Businesses,'' which includes data on the number of health care providers by type with fewer than 20 employees and the numbers of physician, practitioner, and supplier entities with fewer than 10 employees. The Census figures do not differentiate between part-time and full-time employees, and would be expected to result in inflated numbers on the whole when applied to Medicare, but that is acceptable for impact assessment purposes. The Census did not have a category for fewer than 25 employees; fewer than 20 employees was their closest statistic. Overall, the Census data would still be reliable indicators of the anticipated worse case scenario of the maximum number of Medicare providers, physicians, practitioners, and suppliers likely to be impacted by this regulation. The percentages of small providers, physicians, practitioners, and suppliers based on employment numbers for the universe of all U.S. providers, physicians, practitioners, and suppliers should be comparable to the percentage of the subset of those providers that bill the Medicare program.

The Census figures did not include each of the same provider, physician, practitioner, and supplier breakouts as tracked by Medicare's statistics, but the Census figures did include the largest provider, physician, practitioner, and supplier types. The Census figures included 90 percent of all Medicare providers, physicians, practitioners, and suppliers by type. The provider types track differently by CMS and the Census Bureau include regional referral centers, Christian Science Sanitoria, rural health clinics, critical access facilities, and hospices. The ''2002 CMS Statistics'' directory and the 2000 Census data health care establishment totals reported the following:

Provider type	Number of providers	Percentage of providers with less than 20 employees	Likely number excepted
Hospitals	6,031	10.6	639
Home Health Agencies	7,099	69.2	4,913
ESRD Facilities	3,991	16.6	663
Skilled Nursing Facilities	14,841	25.7	3,814
Totals	31,962	31.4	10,029
Type of physician, practitioner or supplier	**Number of providers**	**Percentage of providers with less than 10 employees**	**Likely number excepted**
Clinical Labs	168,333	41.4	69,690
Ambulatory Surgical Centers	3,147	34.9	1,098
Physicians	567,412	70.6	400,593
All Other Practitioners	297,967	71.8	213,940
Totals	1,036,859	66.1	685,321

As there was a 10 percent difference between the Census provider, physician, practitioner, and supplier types and the Medicare provider types, dues to differences in type collection, the numbers impacted would need to be increased by 10 percent to account for the difference. Increased by 10 percent, approximately 11,032 (31.4 percent) of

all Medicare providers, and 753,853 (66.1 percent) of all Medicare physicians, practitioners and suppliers could qualify for an exception of the electronic claim filing requirement based on provider size, leaving approximately 24,126 providers and 386,692 physicians, practitioners, and suppliers (a total of 410,818 potentially affected by the ASCA Medicare requirement nationally).

Approximately 98 percent of providers, and 83 percent or physicians, practitioners, and suppliers already submit claims to Medicare electronically though, and are expected to continue doing so, so the total impacted must be further reduced to determine the approximate number of current paper claim submitters that would likely be affected. It is reasonable to assume that the majority of the paper claims received by Medicare are submitted by smaller providers, physicians, practitioners, and suppliers. As a result, it would not be accurate to reduce the number of affected providers by the full 98 percent of 83 percent. In the absence of reliable statistics to project the current source of all paper claims however, the number of providers potentially affected by the mandatory Medicare electronic claim requirement will be conservatively estimated at a maximum of 50 percent of the entities that would not qualify for a waiver. This leaves 12,063 providers and 193,346 physicians, practitioners, and suppliers (a total of 205,409) that would need to begin submitting claims to Medicare electronically.

Statistics collected for PRA clearance of the Medicare paper claim forms and referenced in the ''Collection of Information Requirements'' section of this preamble indicate that in the absence of a mandatory electronic claim requirement effective for FY 2004, 2.5 million paper claims are expected to be sent to Medicare intermediaries and 133.7 million paper claims are to be sent to Medicare carriers.

Today, many Medicare providers use billing agents or clearinghouses to bill the Medicare program. Many providers, physicians, practitioners, and suppliers that currently submit paper claims have indicated anecdotally that they use paper as they would rather avoid the ''hassle'' of dealing with the multiple electronic claim formats currently required by payers, and the need to have staff keep abreast of the updates to those formats. HIPAA will largely eliminate format differences among payers, but there will continue to be differences concerning use of certain ''situational'' segments and data elements in the formats. It is reasonable to assume that up to half (205,409 × 50 percent = 102,704) of those entities that do not submit claims to Medicare electronically today would prefer to contract with third party to deal with such differences on their behalf.

A small sampling of Medicare contractors indicated an average cost of $0.30 per claim for billing agent and clearinghouse services. The total cost to physicians, practitioners, facilities, suppliers, and other health care providers to use a billing agent or clearinghouse should not be more than $7,055,895 (that is, $.30 × {the sum of 2.5 million paper claims sent to intermediaries as estimated previously for FY 2004 multiplied by the 68.6 percent of providers that would not meet the exception criteria plus 133.7 million paper claims estimated to be sent to carriers multiplied by the 33.9 percent of physicians, practitioners, and suppliers that would not meet the exception criteria}, reduced by 50 percent to account for the assumption that 50 percent of the firms will contract with the third party claims processors).

Finally, in regard to the balance of 102,704 (205,409 × 50 percent) providers, physicians, practitioners, and suppliers that would not be expected to meet the criteria to submit paper claims, we conservatively estimate that approximately 75 percent of these already own personal computers that are used to prepare the paper claim forms they currently submitted to Medicare. Very few hand-written or manually typed claims are submitted to Medicare. Although many paper claim submitters have not used personal computers for electronic billing, they have used them for claim preparation, patient scheduling and other aspects of their practice.

We estimate that at a maximum, the remaining total of 25,676 (25 percent of 102,704) providers, physicians, practitioners, and suppliers will obtain personal computers to allow them to submit their claims directly to Medicare electronically. A recent review of ads in Sunday newspapers indicated that personal computers sufficient to meet the mandatory electronic claim requirement could be obtained for between $500 to $1,000 for hardware (personal computer, monitor, printer, and modem). Billing software is available free or at low cost (less than $25 for shipping and handling) from Medicare. At the average rate of $750, it would cost $19.3 million to purchase 25,676 personal computer systems. More expensive equipment and peripherals could be used, but would not be necessary for basic compliance. Therefore, the total maximum cost should be no higher than $26.4 million ($7.1 million for users of clearinghouses or billing services, and $19.3 million for those that obtain personal computers).

Following the HIPAA savings calculation used in the Transaction Rule, but projected to FY 2004 to account for inflation, a savings of $615 per provider could result in a total provider savings of approximately $15.8 million (that is, 25,676 times $615).

We note that pages 50353 through 50359 of the August 17, 2000 transaction final rule for HIPAA used a 10-year time frame to capture the full extent of costs and savings that could be attributed to the use of the transactions adopted under HIPAA. Data from the 2000 edition of Faulkner and Gray's ''Health Data Directory,'' from a Workgroup for Electronic Data Interchange study report, and from the Department of Labor was used in those calculations to determine total claims in the health care industry, costs to use the transactions electronically, savings expected to be realized, the historical growth rate for claims overall as well as electronic claims, the percentage of electronic health care claims nationally in 2000, and the anticipated inflation rate for the 10-year period.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. According to the Small Business Administration's (SBA's) data, approximately 95 percent of offices of physicians are considered small businesses (see the Small Business Administration's final rule titled ''Small Business Size Standards, Health Care,'' published in the **Federal Register** on November 17, 2000, 65 FR 69432). Most practitioners, facilities, suppliers, and other providers are small entities either because of nonprofit status or because of having revenues of $6 million to $29 million or less in any 1 year. For purposes of the RFA, all physicians, practitioners, facilities, suppliers, and other health care providers that serve Medicare beneficiaries are considered to be small entities. However, as stated earlier, this rule in and of itself does not impose a regulatory burden. The ASCA mandates most aspects of this rule, in particular, the ASCA requires Medicare providers to submit claims electronically and stipulates exceptions that will and may be granted. We did have discretion; however, in setting conditions for exceptions, and believe these exceptions reduce the burden relative to the burden that may have been imposed by ASCA without this enabling regulation.

Individuals and States are not considered small entities. Therefore, no regulatory relief options are considered. A rule has a significant economic impact if it exceeds 3–5 percent of its total costs or revenues according to criterion set by the SBA. The statute exempts many small firms from this rulemaking, affording considerable relief to small entities. At most, small firms that are not exempt will incur an average of either $69 per firm ($7.1 million/102,704 firms) to contract out their claims filing, or purchase computer equipment at an average net cost of $135 per firm ($750 cost − $615 savings.) Therefore, we expect the impact of this rulemaking to fall well below the SBA threshold.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As indicated above, this rule could have an impact on those small rural hospitals that bill Medicare and that do not meet one of the exceptions. However, we do not believe the impact is significant since the cost of compliance is relatively small ($500 to $1,000) and small rural hospitals may be able to qualify for the small provider exception. Therefore, no regulatory impact analysis is required as the impact on small rural hospitals is not significant.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This interim final rule with comment period will not have an impact on State, local, or tribal governments or on the private sector. Instead, the primary impact on State, local, or tribal governments, or the private sector will be that entities that must begin billing Medicare electronically as a result of the ASCA are likely to use that capability to also bill other payers (such as State, local, or tribal governments and the private sector).

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has federalism implications. This interim final rule with comment period will not have a substantial effect on State or local governments for the reasons noted above.

B. Anticipated Effects

1. Effects on Beneficiaries, Physicians, Practitioners, Facilities, Suppliers, and Other Health Care Providers

The anticipated effects on Medicare's beneficiaries will be that additional attention and services may be provided by their health care physician because, for example, electronic billing should reduce administrative paperwork. (This assertion has been made by the medical community in numerous forums over the years, though documentation to this effect is not available.)

The anticipated effects on the entities required to bill electronically will reduce or eliminate paper in their administrative operations, realizing increased efficiencies and indeterminable savings. These savings may be increased by the fact that the Administrative Simplification provisions of HIPAA mandate a standard transaction for electronic claim submissions, and this will facilitate electronic claims submissions to all health care payers. At this time, we do not have additional data to estimate those savings to Medicare physicians, practitioners, facilities, suppliers, and other healthcare providers. As previously stated, there will be a cost incurred by those entities that cannot satisfy one of the exceptions and would be required to bill Medicare in electronic form.

2. Effects on the Medicare and Medicaid Programs

Implementation of this interim final rule with comment period will result in a savings to the Medicare program. If the FY 2004 projected paper claims submissions of 136.2 million (HHS FY 2004 Budget submission to the Congress and estimated electronic media claims rate), are reduced by half and we assume a savings of $1.40 per claim as a result, the program could realize administrative savings of over $95 million per year. (**Note:** The $1.40 per claim savings is the CMS estimate of savings based upon a 1990 Industrial Engineering Study, contracted by CMS (then HCFA). The study documented that FI paper claims cost about $3.30 more to process than electronic claims and, similarly, carrier paper claims cost about $1.00 more to process than electronic claims. Weighing these differences by the 2004 workloads and combining them yields the $1.40 estimated per claim savings.)

We might expect similar types of savings for the States, which administer the Medicaid Program. That is, Medicare providers who become electronic billers due to ASCA may decide to begin billing Medicaid electronically as well. However, this would depend on which of the affected Medicare physicians, practitioners, facilities, suppliers, and other healthcare providers also bill Medicaid. Again, the fact that the Administrative Simplification provisions of HIPAA mandate a standard transaction for electronic claim submissions will facilitate electronic claims submissions to all health care payers.

C. Alternatives Considered

Section 3 of ASCA requires electronic claims submission by those who bill Medicare. There is little room for us to consider alternatives, though we expect that public comment may focus upon further definition regarding the mandatory waivers or regarding those ''unusual cases'' for which the Secretary may waive the mandatory electronic claims submission requirement.

D. Conclusion

As described above, this interim final rule with comment period establishes the requirements for implementing the statutory provisions under section 3 of the ASCA. The law requires, with few exceptions, that physicians, practitioners, facilities, suppliers, and other health care providers that bill Medicare must do so electronically. Coupled with the electronic standard transaction requirements under HIPAA, this rule facilitates greater administrative efficiencies for the Medicare program as well as for those that bill Medicare. There will be a cost incurred for those entities that are unable to meet one of the statutory exceptions, but we expect these initial costs to be offset by increased efficiencies and ongoing lower costs attributable to Medicare claims processing.

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this regulation.

List of Subjects in 42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, CMS proposes to amend 42 CFR chapter VI part 424 as set forth below:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

■ 1. The authority citation for part 424 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 2. In § 424.32, add a new paragraph (d) to read as follows:

§ 424.32 Basic requirements for all claims.

* * * * *

(d) *Submission of electronic claims.*

(1) *Definitions.* For purposes of this paragraph, the following terms have the following meanings:

(i) *Claim* means a transaction defined at 45 CFR 162.1101(a).

(ii) *Electronic claim* means a claim that is submitted via electronic media. A claim submitted via direct data entry is considered to be an electronic claim.

(iii) *Direct data entry* is defined at 45 CFR 162.103.

(iv) *Electronic media* is defined at 45 CFR 160.103.

(v) *Initial Medicare claim* means a claim submitted to Medicare for payment under Part A or Part B of the Medicare Program under title XVIII of the Act for the first time for processing, including claims sent to Medicare for the first time for secondary payment purposes. *Initial Medicare claim* excludes any adjustment or appeal of a previously submitted claim, and claims submitted for payment under Part C of the Medicare program under Title XVIII of the Act.

(vi) *Physician, practitioner, facility, or supplier* is a Medicare provider other than a *provider of services.*

(vii) *Provider of services* means a provider of services as defined in section 1861(u) of the Act.

(viii) *Small provider of services or small supplier* means—

(A) A provider of services with fewer than 25 full-time equivalent employees; or

(B) A physician, practitioner, facility, or supplier with fewer than 10 full-time equivalent employees.

(2) *Submission of electronic claims required.* Except for claims to which paragraph (d)(3) or (d)(4) of this section applies, an initial Medicare claim may be paid only if submitted as an electronic claim for processing by the Medicare fiscal intermediary or carrier that serves the physician, practitioner, facility, supplier, or provider of services. This requirement does not apply to any other transactions, including adjustment or appeal of the initial Medicare claim.

(3) *Exceptions to requirement to submit electronic claims.* The requirement of paragraph (d)(2) of this section is waived for any initial Medicare claim when—

(i) There is no method available for the submission of an electronic claim. This exception includes claims submitted by Medicare beneficiaries and situations in which the standard adopted by the Secretary at 45 FR 162.1102 does not support all of the information necessary for payment of the claim. The Secretary may identify situations coming within this exception in guidance.

(ii) The entity submitting the claim is a small provider or small supplier.

(4) *Unusual circumstances.* The Secretary may waive the requirement of paragraph (d)(2) of this section in such unusual circumstances as the Secretary finds appropriate. Unusual circumstances are deemed to exist in the following situations:

(i) The submission of dental claims.

(ii) There is a service interruption in the mode of submitting the electronic claim that is outside the control of the entity submitting the claim, for the period of the interruption.

(iii) On demonstration, satisfactory to the Secretary, of other extraordinary circumstances precluding submission of electronic claims.

(5) *Effective date.* This paragraph (d) is effective October 16, 2003, and applies to claims submitted on or after October 16, 2003.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: April 22, 2003.

Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Approved: August 12, 2003.

Tommy G. Thompson,

Secretary.

[FR Doc. 03–20955 Filed 8–14–03; 8:45 am]

BILLING CODE 4120–01–P