

fires; protection of patients, staff, and the public; evacuation; and cooperation with fire fighting authorities.

(3) The RNHCI must maintain written evidence of regular inspection and approval by State or local fire control agencies.

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(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: November 21, 2005.

Ann C. Agnew,

Executive Secretary to the Department.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 424

[CMS–0008–F]

RIN 0938–AM22

Medicare Program; Electronic Submission of Medicare Claims

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

ACTION: Final rule.

SUMMARY: This final rule adopts as final, and makes amendments to, the interim final rule published on August 15, 2003. That interim final rule implemented the statutory requirement that claims for reimbursement under the Medicare Program be submitted electronically as of October 16, 2003, except where waived. These regulations identify those circumstances for which mandatory submission of electronic claims to the Medicare Program is waived.

DATES: Effective date: These regulations are effective on December 27, 2005.

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

SUPPLEMENTARY INFORMATION:

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 any expenses for items or 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 health claims transactions (see section 1173(a) of the Act). In the August 17, 2000 **Federal Register** (65 FR 50311), the Secretary of Health and Human Services (the Secretary) published a final rule (generally known as the Transactions Rule) that adopted standards for eight electronic transactions. The transactions standards adopted by that final rule, as subsequently modified by final rule published on February 20, 2003 (68 FR 8381), are codified at 45 CFR part 162, subparts A and I through R.

The HIPAA standards apply to health plans, health care clearinghouses, and certain health care providers; collectively, these entities are known as “covered entities.” An additional category of covered entities—prescription drug card sponsors—was added by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), Pub. L. 108–173. Covered entities are required to comply not only with the standards established by the Transactions Rule, but also with those established via other HIPAA Administrative Simplification rules—such as the Privacy Rule, the Employer Identifier Rule, the Security Rule, and the National Provider Identifier Rule—by the respective applicable compliance dates specified in those rules.

Compliance with the standards for the electronic transactions established by the Transactions Rule was required for all covered entities other than small health plans by October 16, 2002; compliance by small health plans was 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 were not small health plans and that submitted a compliance plan by October 15, 2002. In accordance with 45 CFR 162.900(c), covered entities that were not small health plans and that did not timely submit a compliance plan under ASCA were required to comply by October 16, 2002. Thus, all covered entities, regardless of type, were required to be in compliance no later than October 16, 2003.

Since a significant number of covered entities had expressed strong concern over the health care industry’s state of readiness to conduct fully compliant HIPAA transactions and we wanted to promote compliance while ensuring that cash flow and health care operations would not be unnecessarily disrupted, the Department of Health and Human Services (HHS) issued guidance on the approach CMS would take to enforce the HIPAA electronic transactions and code sets provisions. In accordance with the July 24, 2003 guidance, the Secretary explained that we would focus on voluntary compliance, use a complaint-driven approach, and would not impose penalties on covered entities that deployed temporary contingency plans, if they made reasonable and diligent efforts to become compliant and, in the case of health plans, facilitated the compliance of their trading partners.

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. In 45 CFR 160.102(a)(3), we specify that, in accordance with section 1172(a)(3) of the Act, 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). In 45 CFR 162.923(a), we specify that if a covered entity electronically conducts a covered transaction with another covered entity, it must conduct it as a standard transaction.

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 required Medicare providers to submit Medicare claims electronically by October 16, 2003, unless one of the specified grounds for waiver applies. As the October 16, 2003 deadline approached, we made the decision to implement our own contingency plan after reviewing statistics showing that an unacceptably low number of Medicare providers would likely be capable of submitting compliant claims

by the compliance date. Concerned that many of its trading partners were still completing their transition to HIPAA-compliant transactions, Medicare implemented a contingency plan permitting the submission and processing of claims in electronic formats that were then in use and giving providers additional time to complete the testing processes. Neither CMS's contingency plan for Medicare nor HHS's enforcement guidance modified the October 16, 2003 compliance date for HIPAA transactions.

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 claim transaction) electronically and, thereby, become covered entities. In submitting claims electronically, the providers are required to comply with the applicable HIPAA standard for the health claim transaction. 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 submissions.

Although 86.1 percent of Medicare claims are submitted electronically, the volume of Medicare claims submitted in paper form is substantial. 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 costs they incur. Further, the use of the HIPAA electronic claim standards could result in additional savings if these entities begin electronically billing other payers. However, the statute recognizes that certain circumstances may effectively prevent some providers from transacting claims with Medicare electronically or as standard transactions. ASCA, thus, identifies exceptions to the mandatory submission of electronic Medicare claims. This final rule reiterates and interprets these exceptions.

We considered whether the amendment to section 1862(a) of the Act 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. (Note: The MMA, enacted December 8,

2003, changed and renamed M+C to Medicare Advantage. For discussion purposes and to remain consistent with the interim final rule, the term "M+C" will continue to be used in this preamble.) The question was raised by the provision in section 4 of ASCA that 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) of the Act.

The plain language of section 1862(a) of the Act, 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) of the Act, 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 if those claims were not submitted electronically. 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 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, were required to come into compliance with the regulatory requirements related to transactions no later than October 16, 2003. We understand that all M+C organizations properly filed ASCA compliance plans before October 16, 2002. Therefore, they obtained extensions and had 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 regulations, but would not violate the provisions of section 1862(a)(22) of the Act or the requirements of this regulation. This final rule 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 these providers to any health plans other than Medicare.

Section 902 of the MMA amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of OMB, to establish and publish timelines for the publication of Medicare final regulations based on the publication of Medicare proposed or interim final regulations. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years from the previous publication of the proposed or interim final rule, except under exceptional circumstances.

The MMA also introduced Part D of the Medicare Program. Future rulemaking may be needed to explore the applicability of section 3 of ASCA to Part D. We will initiate such rulemaking, if needed, upon further evaluation as we get closer to the Part D implementation date.

We note that this rule finalizes the provisions of the August 15, 2003 interim final rule. The final rule is, thus, being published within the 3-year time period identified in section 902 of the MMA.

II. Provisions of the Interim Final Rule

Section 3 of ASCA established the requirements and exceptions under the Medicare Program for the mandatory submission of claims in electronic form. In the August 15, 2003 **Federal Register** (68 FR 48805), we published an interim final rule that implemented these statutory requirements.

A. Definitions Used for Electronic Claim Submission

The interim final rule added a new paragraph (d) to § 424.32. Section 424.32(d)(1) specified the following definitions for the purposes of paragraph (d): Claim; electronic claim; direct data entry; electronic media; initial Medicare claim; physician, practitioner, facility, or supplier; provider of services; and small provider of services or small supplier. We defined "claim" to mean the transaction defined at 45 CFR 162.1101(a) (that is, "health care claim"). We specified the definition of "electronic claim" to mean a claim that is submitted via electronic media. In addition, we specified 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)(v) of the interim final rule, we defined 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. This definition also specified that an initial Medicare claim excludes any adjustment or appeal of a previously submitted claim. This final rule adds the phrase “for initial processing” to the definition of “initial Medicare claim” to clarify that the requirement for electronic submission applies to claims that have been previously rejected before being accepted into the Medicare processing system.

In § 424.32(d)(1)(vi), we defined a “physician, practitioner, facility, or supplier” as a Medicare provider other than a provider of services. The final rule adds the words “or supplier” to make the definition precise, so that the term is defined as “a Medicare provider or supplier other than a provider of services.” In § 424.32(d)(1)(vii), we defined a “provider of services” as a provider of services as defined in section 1861(u) of the Act. In § 424.32(d)(1)(viii), we defined a “small provider of services 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 accordance with ASCA.

In § 424.32(d)(2), we specified that, except for claims to which § 424.32(d)(3) or (d)(4) applies, an initial Medicare claim under Part A or Part B or both 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 other health care provider. 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 regulations at 45 CFR 162.923 state 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 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). The reference in section 3 of ASCA to the filing of claims “in electronic form” does not dictate the use of a particular electronic form. Thus, the Medicare program will continue to accept only those forms identified in Chapter 24 of the Medicare Internet Only Claims Processing Manual (IOM Pub. L. 100–04) that we issue. At present, Medicare does not accept claims via the Internet, an extranet or, in many cases, via removable/transportable storage media. This final rule does not change this Medicare policy. The interim final rule stated that an 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.

In the interim final rule, we specified that we will consider claims submitted via a direct data entry screen maintained for Medicare, and as permitted by 45 CFR 162.923, to be electronic claims for purposes of this requirement. Also, we stated that claims transmitted to a Medicare contractor using the free or low cost claims software issued by Medicare fee-for-service plans will be considered electronic claims for purposes of this requirement.

The ASCA provided for exceptions to the requirement for mandatory electronic submission of Medicare claims. In accordance with ASCA, the interim final rule established that the Secretary of HHS could waive the application of the electronic claim requirement in specific cases. To implement the statutory mandate, we provided more explicit requirements that are specified in § 424.32(d). Specifically, § 424.32(d)(3) states that there are two exceptions to electronic submission of initial Medicare claims.

The first exception, specified in § 424.32(d)(3)(i), applies when there is no method available for the submission of an electronic claim. For example, we could not 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 are 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. We identified three other situations that fall into this category:

- 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 has allowed mass immunizers to bill the program using a single claim form with an attached list of beneficiaries to whom a flu vaccine was administered. Many mass immunizers bill electronically, but in a non-standard format. This roster billing simplifies provider billing but is not available in electronic form under the Transactions Rule.

- Claims for payment under Medicare demonstration projects. Medicare demonstration projects often allow for unusual situations not normally handled by the transactions standards; and

- Claims where more than one health plan is responsible for payment before Medicare. The interim final rule indicated that efforts were underway to resolve the confusion in the reporting of per service payments by more than one primary payer and allowed these claims to continue to be submitted to Medicare on paper for the time being. Although a number of alternatives were considered, a clear process for electronic billing of Medicare in this case is not yet finalized. Once a solution is reached, we will then notify the public of the effective date of the change.

Providers to whom an exception does not apply will then be required to submit Medicare claims electronically. In the interim final rule, we established that specific program guidance would be issued to Medicare providers concerning submission of these claims on paper effective October 16, 2003. We stated that we would also issue specific guidance or regulations, as necessary, informing covered entities if this or another exception no longer applies.

The second exception, described in § 424.32(d)(3)(ii), provided that electronic submission would be waived when the entity submitting the claim is a small provider of services or small supplier. The statute is quite specific as to the size requirements, and the interim final rule simply incorporated the statutory requirements. This final rule

makes a slight technical revision, in order to use a defined term consistently.

D. Unusual Cases

In the interim final rule, we established that the Secretary may waive the electronic submission requirement in certain unusual situations as the Secretary finds appropriate. In § 424.32(d)(4), we specified that such an exception would exist in the following three situations:

- The submission of dental claims. This exception is being included because, under HIPAA, dentists who are covered entities 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.

- 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 would apply only if the physician, practitioner, facility, supplier, or other health care provider temporarily loses electricity, or telephone or other communication service. If electricity, telephone, or other communication services exist, but one or the other 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 power or communication service.

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

The interim final rule specified that entities would 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 would have to be submitted to a Medicare FI or carrier when an entity did *not* meet the mandated exceptions at § 424.32(d)(3), or the specified discretionary waiver criteria at § 424.32(d)(4)(i) and (d)(4)(ii), but believed there were other extraordinary circumstances that precluded its submission of electronic claims. We also proposed to 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. This program guidance was issued on December 19, 2003 (Transmittal 44, CR 2966, Instructions

for the Mandatory Electronic Submission of Medicare Claims), and may be found at www.cms.hhs.gov/manuals/. Publication of this final rule will result in some changes to Transmittal 44, CR 2966, which will be reissued following publication of this final rule.

This final rule adds two more unusual situations under § 424.32(d)(4) for which an exception would exist. Specifically, the requirement to submit electronic claims may be waived when the entity submitting the claim (1) submits, on average, less than 10 claims per month, or (2) furnishes services only outside of the U.S. territory. See our response to comments in section III of this preamble for further discussion regarding these additional exceptions.

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.

We specified that the Secretary may review entities that bill Medicare non-electronically. We stated that entities determined to be in violation of the statute or the interim final rule would be subject to claim denials, overpayment recoveries, and applicable interest on overpayments.

F. Effective Date

In accordance with section 3(b) of ASCA, we specified, in § 424.32(d)(5) of the regulations, that the effective date for these amendments would be for claims submitted on or after October 16, 2003.

III. Analysis of and Responses to Public Comments

We received 17 timely public comments on the August 15, 2003 interim final rule. Based upon some of the comments we received from members of the health care provider community who bill Medicare, there remain questions about Medicare's electronic claim submission requirement and how this rule applies in certain situations. Additional information was provided through Medicare manual instructions to FIs and carriers (Transmittal 44, CR 2966, December 19, 2003, which may be found at www.cms.hhs.gov/manuals/). Several providers are uncertain about how to determine if they meet the definition of "small provider of services or small supplier," especially when

deciding who should be included in the "full time equivalent" (FTE) employee calculation. Furthermore, some providers have questions concerning whether they are required to submit a request to HHS for a small provider waiver, which would allow them to continue submitting their claims to Medicare on paper.

A. General Issues

Comment: One commenter stated that the August 15, 2003 interim final rule did not provide sufficient time for providers to comply with the October 16, 2003 statutory effective date and that we should change the implementation date.

Response: We understand the commenter's concern. However, we are not able to change the effective date of implementation and compliance, because the October 16, 2003 effective date is mandated by the statute.

B. Determining Small Provider Status

To qualify for a waiver as a small provider of services or small supplier, and thus, be permitted to continue billing Medicare on paper, the entity submitting a claim must be either: (1) A provider of services with fewer than 25 FTEs that submits its claims to a Medicare FI; or (2) a physician, practitioner, facility, or supplier with fewer than 10 FTEs who bills a Medicare carrier or Durable Medical Equipment Regional Carrier (DMERC).

Comment: Several commenters believe many in the provider community remain unaware that providers do not need to request a waiver for a small provider exception from Medicare electronic claims submission. In addition, other commenters requested a small provider waiver.

Response: Providers who in good faith believe they qualify as "small providers of services or small suppliers" automatically qualify for the small provider waiver unless, upon subsequent review, the Department determines that the waiver requirements in fact are not met. In that case, if the Department finds that none of the exceptions applies, the provider must submit all claims to Medicare electronically. Providers must assess their own situation and determine for themselves whether they meet the small provider criteria.

Small providers of services and small suppliers may elect to submit some of their claims to Medicare electronically, and some claims on paper. Submission of some claims electronically does not revoke or cancel their status as a small provider of services or small supplier,

nor obligate them to submit all of their claims electronically. (More information about this will be published through the Medicare contractors. The first in a series of publications was Transmittal 44, CR 2966 dated December 19, 2003.)

Comment: Several commenters requested additional guidance on the term "FTE," including direction on who is considered an FTE and how the number of FTEs should be calculated for a small provider of services or small supplier. One commenter suggested that only clinical staff should be included in the FTE count. Other commenters believe owners of practices should not count toward the FTE total.

Response: ASCA and its implementing regulation do not modify pre-existing laws or employer policies defining full-time employment. Employers have established policies and practices, subject to State and Federal laws, which define "full-time equivalent" and provide methods for calculating the number of hours their employees must work on average on a weekly, biweekly, monthly, or yearly basis to constitute a "full-time equivalent" employee. Some employers classify employees who work an average of 32 hours per week as one FTE, whereas other employers consider only employees who work 35 to 40 hours per week on average as one FTE. An employee who works an average of 40 or more hours a week would virtually always be considered full-time and one FTE, but employees who work fewer hours weekly could also be considered full-time and one FTE according to the policies of, and laws applicable to, a different employer.

Everyone on staff for whom a health care provider withholds taxes and files reports with the Internal Revenue Service (IRS) using an Employer Identification Number (EIN) is considered an employee including, if applicable, the physician(s) who owns a practice and provides hands-on services, and those support staff who do not furnish health care services but do retain records of, perform billing for, order supplies related to, provide personnel services for, and otherwise perform support services to enable the provider to function. Unpaid volunteers would not be considered employees for purposes of calculating FTEs.

Individuals who perform services under independent contract for a provider, such as individuals employed by a billing agency or medical placement service, for whom a provider does not withhold taxes, are not considered members of a provider's staff for FTE calculation purposes when determining whether a provider of services or

supplier can be considered as "small" for electronic billing waiver purposes.

Medical staff members may sometimes work part-time, or may work full-time but their time is split among multiple providers. Part-time employee hours must also be counted when determining the number of FTEs employed by a provider. For example, if a provider has a policy that anyone who works at least 35 hours per week on average qualifies as full-time (that is, as one FTE), and has five full-time employees and seven part-time employees, each of whom works 25 hours a week, that provider would have ten FTEs ($5 + [7 \times 25 = 175 \text{ divided by } 35 = 5]$).

In some cases, the employer identification number (EIN) of a parent company may be used to file employee tax reports for multiple providers under multiple Medicare provider numbers. In that instance, it is acceptable to consider only those staff, or staff hours worked for a particular provider as identified by Medicare provider number to calculate the number of FTEs employed by that provider. For example, ABC Health Care Company owns hospital, home health agency (HHA), ambulatory surgical center (ASC), and durable medical equipment (DME) subsidiaries. Some of those providers bill intermediaries and some carriers. All have separate provider numbers, but the tax records for all employees are reported under the same EIN to the IRS. There is a company policy that staff must work an average of 40 hours a week to be considered full-time.

Some of the same staff split hours between the hospital and the ASC, or between the DME and HHA subsidiaries. To determine total FTEs by provider number, it is acceptable to base the calculation on the number of hours each staff member contributes to the support of each separate provider by provider number. First, each provider would need to determine the number of staff members who work on a full-time basis under a single provider number only; not more than 40 hours a week should be counted for these employees. Then each provider would need to determine the number of part-time hours a week worked on average by all staff who furnished services for the provider on a less than full-time basis, and divide that total by 40 hours to determine their full-time equivalent total. If certain staff members regularly work an average of 60 hours per week, but their time is divided 50 hours to the hospital and 10 hours to the ASC, for FTE calculation purposes, consider the person as one FTE for the hospital and .25 FTE for the ASC.

In some cases, a single provider number and EIN may be assigned, but the entity's primary mission is not as a health care provider. For instance, a grocery store's primary role is the retail sale of groceries and ancillary items including over-the-counter medications, but the grocery store has a small pharmacy section that provides prescription drugs and some DME to Medicare beneficiaries. A large drug store has a pharmacy department that supplies prescriptions and DME to Medicare beneficiaries, but most of the store's revenue and most of their employees are not involved with prescription drugs or DME and concentrate on non-related departments of the store, such as groceries, film development, cosmetics, electronics, cleaning supplies, etc. A county government uses the same EIN for all county employees but their health care provider services are limited to furnishing of emergency medical care and ambulance transport to residents.

For FTE calculation purposes, it is acceptable to include only those staff members of the grocery store, drug store, or county government involved with, or that support the provision of, health care in the FTE count when assessing whether a small provider waiver may apply. Support staff who are to be included in the FTE calculation in these instances include, but are not necessarily limited to, those that restock the pharmacy or ambulance, order supplies, maintain patient records, or provide billing and personnel services for the pharmacy or emergency medical services department if under the same EIN. FTEs should be calculated according to the number of hours on average that each staff member contributes to the department that furnishes the services or supplies for which the Medicare provider number was issued.

Neither unpaid volunteers nor individuals that perform services for a provider under independent contract, such as individuals employed by a billing agency or medical placement service, for whom a provider does not withhold taxes, should be considered toward an entity's FTE count when determining if a provider of services or supplier can be considered as "small" for electronic billing waiver purposes.

C. Contingency for Paper Billers

Comment: Several commenters requested that the Medicare HIPAA contingency plan extend to paper claims so as to avoid cash flow problems among providers.

Response: The ASCA enacted on December 27, 2001 (Pub. L. 107-105)

requires the electronic submission of Medicare claims in an electronic form specified by the Secretary of the HHS. The statute waives this requirement only in limited situations, which are detailed in § 424.32 of this regulation. The “electronic form” specified by the Secretary generally means the electronic transactions and code sets standards adopted as part of the HIPAA as detailed in 45 CFR parts 160 and 162.

In response to HHS contingency plan guidance for the electronic transactions and code sets standards under HIPAA, issued on July 24, 2003, Medicare announced its HIPAA contingency plans on September 23, 2003. Medicare’s contingency plans allowed for the submission of claims in non-compliant electronic formats on and after October 16, 2003, for an unspecified period of time. However, Medicare has revised its contingency plan; it is paying electronic, HIPAA non-compliant claims no sooner than 27 days after receipt, beginning with claims received on or after July 1, 2004. Continued paper submission of Medicare claims is not a part of Medicare’s HIPAA transactions contingency plan. The statute affords no latitude for those who do not meet one of the exceptions, but Medicare will take into consideration the good faith efforts by a provider to comply with the electronic billing requirement when enforcing the provision.

Comment: One commenter expressed concerns that Medicare would not be able to handle an increase in paper claims submission if a larger portion of providers eligible for the “small provider of services or supplier” waiver opted to continue, or drop back to, paper claims submission.

Response: Approximately 98 percent of claims submitted to FIs, and 83 percent of carrier claims are electronic. With the benefits and efficiencies gained through electronic billing, we do not believe that electronic billers who are eligible to bill on paper will indeed revert to paper. Paper claims are more cumbersome to complete and are paid less timely than electronic claims. Moreover, we do not expect difficulty with Medicare contractors’ ability to handle paper claims if there were an increase in volume. Since the interim final rule’s October 16, 2003 effective date, Medicare contractors have not experienced any problems in receiving and processing electronic claims, and we have not observed any increase in electronic billers who are eligible to bill by paper reverting to paper claims submissions.

D. Definition of Initial Medicare Claim

We received a number of comments related to our definition of “initial Medicare claim.” In the interim final rule, this term was defined in § 424.32(d)(1)(v) 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 for secondary payment purposes. Some disagree with our decision to require electronic submission of Medicare Secondary Payer (MSP) claims. We have responded to comments submitted on this definition below and provided added clarity. Some commenters also expressed concerns with their ability to submit an electronic MSP claim with a paper attachment.

Comment: We received one comment on resubmission of initial Medicare claims. The commenter was concerned that claims submitted before the compliance deadline of October 16, 2003 on paper and then resubmitted after the deadline on paper would be rejected.

Response: We understand the concerns of the provider community regarding resubmission of claims previously submitted on paper in an electronic format; however, the statute does not afford us any flexibility in allowing for paper claims submission following the compliance deadline.

We have interpreted the intent of the statute to mean claims submitted to the Medicare claims processing system for the first time, including claims submitted after having been previously rejected (which were not previously considered as submitted claims since they were never accepted into the processing system), claims with paper attachments, demand bills, claims where Medicare is secondary and there is only one primary payer, and non-payment claims, as claims that must be submitted electronically barring any waiver or exception. Initial Medicare claims do not include adjustments submitted to intermediaries on previously submitted claims or appeal requests.

Comment: One commenter expressed concerns with our inclusion of a claim sent to Medicare for secondary payment (MSP) purposes in our definition of “initial Medicare claim.” They argued that although primary claims and MSP claims use the same HIPAA 837 standard, the HIPAA regulations make a distinction between the two transactions and, as a result, MSP claims should be treated differently than other Medicare claims.

Response: While MSP claims were not specifically highlighted, the statutory

language does not exclude them from consideration as initial Medicare claims. Furthermore, we do not believe that MSP claims should be treated as a different type of claims transaction for purposes of Medicare electronic claims submission, because submission of a secondary claim would still constitute an initial submission of a claim to Medicare. Therefore, we have interpreted the statute to mean they must not be excluded from the electronic submission requirement. Our definition of an “initial Medicare claim” is consistent with this interpretation.

Claims submitted to Medicare when there is more than one primary payer must be submitted on paper as it is difficult to submit service level data for more than one primary payer electronically at this time. The only alternative is for providers to submit those claims to Medicare on paper with copies of the explanation of benefits (EOBs)/remittance advices (RAs) from the primary payers attached.

Comment: We received comments from providers concerning submission of EOBs/RAs. For instance, one commenter was under the impression that an 835 electronic remittance advice transaction is needed to submit an 837 MSP claim. The commenter proposed as an alternative that the electronic submission of claims for which Medicare is secondary be phased in and only required when providers receive an 835.

Response: In order for a provider to be reimbursed for an MSP claim, the provider must submit to Medicare certain payment information contained in the EOB/RA from the primary payer(s). We encourage providers to work with their payers to receive the remittance advice in the 835 electronic format, but that is not mandated by HIPAA or ASCA. A provider may receive this information from the primary payer(s) either on paper or electronically. A provider does not need to receive an 835 electronic remittance advice transaction from a primary payer, however, in order to generate a secondary claim for Medicare.

E. Attachments

Comment: We received some comments on timely reimbursement of electronic claims submitted with paper attachments. In one case, a provider believed that it was unable to receive reimbursement for an electronic claim unless a paper claim was also submitted.

Response: Transmittal 44, CR 2966, December 19, 2003, required Medicare contractors to issue further guidance to providers and submitters on the

submission of electronic claims when there are paper attachments. Providers and submitters who experience difficulty getting their electronic claims that have paper attachments processed must first contact their Medicare contractor. If problems persist, providers and submitters are encouraged to contact their regional CMS office to troubleshoot these issues. Phone numbers for Medicare contractors and CMS regional offices can be found on our Web site at: <http://www.cms.hhs.gov/physicians/default.asp>.

Comment: Another commenter was concerned with Medicare connecting paperwork and hard copy EOBs with an electronic claim, resulting in untimely reimbursement and extra follow-up time.

Response: Once the electronic claims attachment standard is adopted and entities have properly implemented it, this issue will be resolved. In the meantime, and prior to the claims attachment standard compliance date, paper attachments must be properly associated with the corresponding electronic claims by incorporating correct and appropriate data and indicating in the electronic claims transaction that separate paper documentation is being sent. Separate submission of electronic claims and related paper attachments should consequently not cause a discernable delay in payment of claims. Providers and other electronic claim submitters are advised to contact the Medicare contractor to which they submit their claims if they have further questions about the locally published process.

Pending issuance of the future instructions concerning submission of medical records for electronic claims, providers and Medicare contractors can continue current policies and practices regarding submission of attachments with claims, whether in a proprietary format, on paper, via fax, or by other means.

F. Unusual Cases

While commenters expressed their support for electronic claims submission, they were also pleased with the flexibility afforded by the outlined exceptions, which permit continued paper claims submission such as in the case of roster vaccinations billing and certain Medicare demonstration claims. We received a number of comments on "unusual cases," asking for further clarity.

Comment: One commenter stated the interim final rule was unclear concerning whether paper claims would be allowable after the compliance

deadline. The commenter proposed designating the HIPAA transition period to a largely electronic submission environment for Medicare, an "unusual case."

Response: The "unusual case" provision is intended to operate as an exception to a situation in which Medicare providers are generally submitting claims electronically. The commenter, however, proposes making the exception to be the norm, which would appear to be contrary to what the Congress intended.

Comment: Another commenter suggested we expand the criteria for the service interruption to include power outages, which result in a phone or communication service interruption.

Response: We have interpreted an "unusual case" exception to be one applied to a temporary situation outside of a provider's control that effectively precludes electronic submission of claims. For a situation to fall under an "unusual case" exception, the circumstances must be truly out of the ordinary and they must genuinely prevent the provider from complying with the applicable electronic submission requirement.

In the August 15, 2003 interim final rule, we described three situations that we believe meet the criteria for an unusual case exception. The three situations we listed were submission of dental claims, a service interruption outside the control of the submitter, and other extraordinary circumstances deemed satisfactory to the Secretary.

We also specified that the service interruption exception is limited to submitters who have experienced a loss of phone or communication service. We agree with the commenter that it may be possible for an interruption in the mode of service used to submit a claim to occur resulting from something other than inclement weather or phone company problems. We further recognize that a loss of power could occur that does not result in the loss of the use of a phone or other communication services but precludes or severely inhibits a submitter from sending claims electronically. In this rare and unanticipated situation, a waiver may be granted for service interruption. This is addressed in Medicare manual instructions, Transmittal 44, CR 2966, December 19, 2003.

Based on comments received and our assessment of the reasonableness of an entity's ability to comply, we have identified the following two additional "unusual case" situations we consider to be eligible for a waiver under § 424.32(d)(4). First, an unusual case is

deemed to exist when an entity submits fewer than 10 claims to Medicare per month on average. We believe entities that submit such low volumes of Medicare claims are "unusual cases" in that the volume does not support mandating the acquisition of hardware/software to submit claims electronically. The exception for small providers indicates to us the Congress's intention that the electronic submission requirement not apply to providers for whom the electronic submission requirement of claims would be truly burdensome. This would be the case for providers who submit fewer than 10 claims per month, as the cost of converting their billing systems for so few claims would be uneconomic. If the volume increases, then electronic claim submission would be required, unless another exception applies. This is self-assessable and the entity need not submit a waiver request. Second, it is deemed to be an unusual case when the entity submitting a claim furnishes services only outside of the U.S. territory. The HIPAA transactions and code sets standards are consensus-based, American National Standards Institute (ANSI)-accredited standards that rely upon hardware and software that meet certain specifications, which may not be readily available outside of the U.S. territory. We believe that entities furnishing services solely outside of the U.S. in many cases could not properly submit electronic claims. Moreover, we think those entities are few in number and truly constitute an unusual case. This is also self-assessable and the entity need not submit a waiver request. Section 424.32(d)(4) is revised to include these two additional "unusual case" situations.

Instructions to the Medicare contractors that describe how to go about requesting an "unusual case" waiver were issued December 19, 2003 (Transmittal 44, CR 2966).

Comment: One commenter urged Medicare contractors to furnish all providers and mass immunizer billers and suppliers with free electronic roster billing software, in order to reduce dependence on paper roster billing and increase cost savings to the program. Another commenter suggested there remains a need for continued outreach to educate providers on these topics.

Response: We are considering these suggestions; however, claims submission for roster billing for vaccinations is still considered exempt from the electronic claims submission requirement. To the extent certain Medicare contractors' software permits electronic submission of roster bills, we

encourage providers to use it; however, it is not required.

We have issued instructions to the Medicare contractors that describe in greater detail how this regulation is operationalized, including instructions for requesting an "unusual case" waiver (refer to Transmittal 44, CR 2966, dated December 19, 2003). In addition, Medicare contractors will be instructed to include information on their provider Web sites and in their newsletters that addresses these and other issues pertinent to operationalization of the regulation.

G. Testing With Medicare

Comment: Several commenters expressed concerns regarding low HIPAA transaction testing rates between providers and Medicare.

Response: Medicare testing has increased over the past several months and rose steadily in the weeks leading up to the HIPAA compliance deadline. As of September 10, 2004, approximately 97.7 percent of inbound claims were being submitted to Medicare in the HIPAA-compliant format.

Medicare invoked its HIPAA contingency plan to afford added flexibility to providers and submitters who were not ready to submit claims in the HIPAA electronic format on the deadline of October 16, 2003, to continue to prepare for the electronic claims submission requirement in the adopted formats. Many Medicare contractors were ready to test the 837 and 835 for 6 or more months before the October 16, 2003 deadline. Medicare's revised HIPAA contingency plan encourages further HIPAA compliance because, effective July 1, 2004, non-compliant electronic claims are paid no sooner than 27 days after the date of receipt while compliant claims are paid sooner.

Comment: Another commenter requested that Medicare relax the technical edits to HIPAA transactions so that claims may continue to be processed after the deadline.

Response: We believe that Medicare has tried to make reasonable accommodations regarding its technical edits, while remaining considerate of how changes in its claims processing systems may affect various other submitters (some of whom could be adversely affected by inappropriate technical edits).

H. Impact of HIPAA Standards

Comment: Several commenters expressed concerns surrounding the overall level of readiness by the industry for implementing the HIPAA

transaction and code set standards due to possible industry variations in the interpretation of the standards. They were concerned that unresolved questions pertaining to complying with the HIPAA standards could impact a provider's ability to submit claims electronically and, therefore, comply with the Medicare electronic claims submission requirement.

Response: We recognize that a number of HIPAA implementation issues exist and present obstacles to HIPAA compliance; however, these issues and obstacles extend beyond the scope of this regulation. We are addressing these concerns through other channels. Medicare's HIPAA contingency plan may afford some additional latitude to entities as they work toward compliance with the HIPAA standards. In the meantime, Medicare's contingency plan allows for providers, under specified circumstances, to continue to send HIPAA non-compliant electronic claims to Medicare and, therefore, facilitate compliance with the ASCA mandate.

I. Enforcement

Comment: One commenter identified a few issues related to compliance with HIPAA's electronic transactions and code sets standards such as a request for new data elements, which could impact compliance with the Medicare electronic claims submission requirement.

Response: For any change to a standard to become effective and compliance required, the designated standard maintenance organization would first have to hold public hearings and ultimately the Secretary would need to adopt the change formally.

Comment: Another commenter suggested we find an alternate term for "audit" when discussing enforcement.

Response: We accept this comment; therefore, in the future we will reference the Secretary's ability to "audit" an entity as the ability to "review" an entity for compliance. In addition, the preliminary enforcement process will be conducted on a prospective basis and will focus on providers that appear to be submitting extraordinarily high numbers of paper claims. If a review establishes that a provider is submitting paper claims without properly qualifying for a waiver, the provider will be notified that any paper claims submitted after a certain date will be rejected by Medicare. However, providers will be afforded a reasonable amount of time under the circumstances to come into compliance with the electronic claim submission requirement.

A future Medicare manual instruction to Medicare contractors will explain the criteria for review and the enforcement requirements for providers that are determined to have incorrectly submitted paper claims.

J. Costs To Convert From the Submission of "Paper Claims" to "Electronic Claims"

Comment: One commenter requested that we provide a more realistic estimate of the costs associated with converting from paper claims submission to electronic claims submission. Several commenters believe that the requirement to submit Medicare claims electronically represents a costly expense without the potential for reimbursement to providers.

Response: When considering this comment, we reviewed again the basis for the cost estimate and considered further possible paperwork burden and capital investment issues in the impact analysis of the interim final rule. We concluded that the cost estimate remains the most accurate, given the data that were available.

Due to the high number of Medicare claims already submitted electronically and the waivers issued for "small providers," moderately sized providers are most likely to be affected by this requirement. While we do agree that a provider's staff will need some time to become fully familiar and proficient with the use of the free/low cost Medicare billing software, a physician's office (which presently submits claims on paper) can purchase hardware to enable compliance with this requirement for less than \$1,000. Although the electronic conversion will not be reimbursed, we continue to believe that we have tried to provide the most economical software for providers, and we will even provide free technical support on the installation and usage through our Medicare contractors.

K. Outside the Scope of This Rule

Comment: One commenter requested that Medicare guidance communications or program changes to physicians be completed on paper rather than electronically.

Response: Although we appreciate this commenter's concern, because these issues were not addressed in the August 15, 2003 interim final rule, we are not able to address this concern in this final rule.

Comment: Another commenter suggested that we reimburse for nursing service claims.

Response: Although we appreciate the commenter's concerns, nursing service claim reimbursement was not covered

in the August 15, 2003 interim final rule. Therefore, we are unable to address this concern in this final regulation.

IV. Provisions of This Final Rule

With some minor editing and modification to include two additional "unusual cases" for an automatic exception and changed "unusual circumstances" to "unusual cases", we are adopting all of the provisions set forth in the August 15, 2003 interim final rule as final.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 30-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 hours (form CMS-1450). The current approval expires 12/31/05.

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 hours (form CMS-1500). The current approval expires 3/31/06.

Approximately 205,409 providers and suppliers will be affected by this final rule and will have to change the format

for the claims they submit. 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 may cost them approximately \$.30 per claim, or that of purchasing computer equipment, which we estimate at \$500 to \$1,000.

In the final rule published to implement the electronic transactions and code sets standards, we estimated that it would take an average of 10 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 0.5 minutes to submit electronically; form CMS-1500 takes 15 minutes and 1 minute, respectively.

If 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 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 us).

As required by section 3504(h) of the PRA of 1995, we have submitted 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 these information collection and recordkeeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Jimmy Wickliffe, CMS-0008-F,

Room C5-11-04, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Christopher Martin, Desk Officer, CMS-0008-F.

Comments submitted to OMB may also be e-mailed to the following address: e-mail: christophermartin@omb.eop.gov; or faxed to OMB at (202)395-6974.

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, we use a pre-statute baseline; therefore, all costs and benefits identified in this impact analysis are attributed to this final rule. Nevertheless, the ASCA mandates most aspects of this final rule. In particular, the ASCA requires Medicare providers to submit claims electronically and stipulates the exceptions that will and may be granted. However, we did have discretion in setting the conditions for exceptions, and believe that these exceptions reduce the burden relative to the burden that was imposed by ASCA without this implementing 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 that 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 (EMC) rate 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 FY 2004, the first year of implementation of mandatory Medicare electronic media claims (EMC). Using workload growth projections from our 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. 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, tracked differently by the Census Bureau and us, include regional referral centers, Christian Science Sanitoria, rural health clinics, critical access facilities, and hospices. The "2002 CMS Statistics" directory (number of providers) and the 2000 Census data health care establishment totals (percentage of providers with less than 20 employees) 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, due to

differences in type of 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 of physicians, practitioners, and suppliers already submit claims to Medicare electronically, 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 or 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.

Prior to HIPAA, many Medicare providers used billing agents or clearinghouses to bill the Medicare program. Many providers, physicians, practitioners, and suppliers that submitted paper claims indicated anecdotally that they used paper as they would rather avoid the "hassle" of dealing with the multiple electronic claim formats required by payers, and the need to have staff keep abreast of the updates to those formats. HIPAA largely eliminates format differences among payers, but there will always 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 a 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, $\$.30 \times \{\text{the sum of 2.5 million paper claims sent to intermediaries as estimated previously for FY 2004 multiplied by the 68.6 percent of providers that would not meet the exception criteria, plus 133.7 million paper claims estimated to be sent to carriers multiplied by the 33.9 percent of physicians, practitioners, and suppliers that would not meet the exception criteria}\}$).

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 submit 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 claims 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 computer costs in the marketplace indicated that personal computers sufficient to meet the mandatory electronic claim requirement could be obtained for \$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 the Transaction Final Rule (65 FR 50353 through 50359) used a 10-year timeframe 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.

Thus, we estimate that the total cost-plus savings would be approximately \$42.2 million, which is less than the \$100 million threshold for an RIA. Again, these total costs and savings attributable to ASCA could be even less if we were able to factor in the impact HIPAA may have on electronic billing growth.

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 the 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 implementing regulation. If this final rule has an average annual impact that exceeds 3 to 5 percent of total costs or revenues, it would be considered significant according to the Department of Health and Human Services (HHS) Guidelines. However, at a cost of \$750 per computer and savings of \$615 (\$750-\$615), we expect this to fall significantly below the revenue rule given by the HHS. Therefore, we have determined that this rule will not have a significant economic impact on a substantial number of small entities. Individuals and States are not considered small entities. Therefore, no regulatory relief options are considered.

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 expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$100 million. This final rule will not have an impact of that size 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 publishes a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications.

This final rule will not have a substantial effect on State or local governments for the reasons noted in this section of this final rule.

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 was made by the medical community in numerous forums over the years, although 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 final rule 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 our 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 the ASCA mandated that all Medicare claims on or after October 16, 2003, be submitted electronically. Since the statute requires the electronic submission of claims, no alternatives to electronic submission were considered. However, we are interpreting the statutory provisions of the ASCA to allow for reasonable and limited exceptions to the electronic submission requirement.

D. Conclusion

As described above in section VI.A., this final rule establishes the requirements for implementing the statutory provisions under section 3 of the ASCA. The statute requires, with few exceptions, that physicians, practitioners, facilities, suppliers, and other health care providers that bill Medicare 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 lower ongoing 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, the interim rule amending 42 CFR part 424 that CMS published on August 15, 2003 (68 FR 48805) is adopted as a final rule with the following amendments:

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. Amend § 424.32 by—

■ A. Revising paragraphs (d)(1)(v); (d)(1)(vi); (d)(3)(ii), and (d)(4) introductory text.

■ B. Redesignating (d)(4)(iii) as paragraph (d)(4)(v).

■ C. Adding paragraphs (d)(4)(iii) and (iv).

The revisions and additions read as follows:

§ 424.32 Basic requirements for all claims.

(d) * * *

(1) * * *

(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 initial 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 or supplier other than a provider of services.

* * * * *

(3) * * *

(i) * * *

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

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

* * * * *

(iii) The entity submitting the claim submits fewer than 10 claims to Medicare per month, on average.

(iv) The entity submitting the claim only furnishes services outside of the U.S. territory.

* * * * *

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

Dated: May 2, 2005.

Mark B. McClellan,
Administrator, Centers for Medicare & Medicaid Services.

Approved: August 15, 2005.

Michael O. Leavitt,
Secretary.

Editorial Note: This document was received at the **Federal Register** on November 17, 2005.

[FR Doc. 05–23080 Filed 11–23–05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

Centers for Medicare & Medicaid Services

45 CFR Parts 144, 146, 148, and 150

[CMS–4091–F]

RIN 0938–AN35

Federal Enforcement in Group and Individual Health Insurance Markets

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

ACTION: Final rule.

SUMMARY: This rule makes final an interim final rule that details procedures we use for enforcing title XXVII of the Public Health Service Act as added by the Health Insurance Portability and Accountability Act of 1996, and as amended by the Mental Health Parity Act of 1996, the Newborns’ and Mothers’ Health Protection Act of 1996, and the Women’s Health and Cancer Rights Act of 1998. Specifically, we are responsible for enforcing title XXVII requirements in States that do not enact the legislation necessary to enforce those requirements, or otherwise fail to substantially enforce the requirements. We are also responsible for taking enforcement actions against non-Federal governmental plans. The regulation describes the process we use in both enforcement contexts. This final rule deletes an appendix to the interim rule that listed examples of violations of title XXVII and corrects the description of a cross-reference, but makes no substantive changes to the interim final rule.

DATES: These regulations are effective on December 27, 2005.

FOR FURTHER INFORMATION CONTACT: David Mlawsky (877) 267–2323, ext. 61565.

SUPPLEMENTARY INFORMATION

I. Background

Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) created a new title XXVII of the Public Health Service (PHS) Act (42 U.S.C. 300gg, *et seq.*) that requires group health plans and health insurance issuers to provide certain guarantees for availability and renewability of health coverage in the group and individual health insurance markets.

HIPAA created a series of parallel provisions that were placed in the Employee Retirement Income Security Act (ERISA), which is within the jurisdiction of the Department of Labor; the Public Health Service (PHS) Act, which is within the jurisdiction of the Department of Health and Human Services; and the Internal Revenue Code, which is within the jurisdiction of the Department of the Treasury. These “shared provisions” set forth Federal requirements relating to portability of and access to group health plan coverage, as well as group health insurance coverage provided by issuers. The shared provisions contain rules limiting the use of preexisting condition exclusion periods, and prohibiting discrimination against participants and beneficiaries based on health status.

Section 104 of Title I of HIPAA requires that the Secretaries of the three Departments ensure through an interagency Memorandum of Understanding (MOU) that regulations, rulings, and interpretations issued by each of the Departments relating to the same matter over which two or more departments have jurisdiction, are administered so as to have the same effect at all times. Under section 104, the Departments, through the MOU, are to provide for coordination of policies relating to enforcement of the same requirements in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement. The Secretaries of the three departments signed and published the MOU in 1999 (64 FR 70164).

HIPAA also added certain provisions governing insurance in the group and individual markets, and with respect to non-Federal governmental plans, which are contained only in the Public Health Service Act and are not within the regulatory jurisdiction of the Department of Labor or the Department of the Treasury.

Under section 101(b) of HIPAA the Department of Labor is not authorized to enforce any of the portability requirements of part 7 of ERISA (the “shared” provisions) against a health insurance issuer offering health