Dated: August 4, 2003.

**Donald S. Welsh,**

*Regional Administrator, Region III.*

■ For the reasons set out in this document, 40 CFR part 300 is amended as follows:

## PART 300—[AMENDED]

■ 1. The authority citation for part 300 continues to read as follows:

**Authority:** 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p. 351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

## Appendix B—[Amended]

■ 2. Table 1 of Appendix B to Part 300 is amended by removing the site for ''Resin Disposal, Jefferson Borough, PA.''

[FR Doc. 03–21596 Filed 8–21–03; 8:45 am]

BILLING CODE 6560–50–P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

## Centers for Medicare & Medicaid Services

## 42 CFR Part 413

**[CMS–1199–F]**

**RIN 0938–AL51**

## Medicare Program; Electronic Submission of Cost Reports

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

**ACTION:** Final rule.

**SUMMARY:** This final rule amends regulation by requiring that, for cost reporting periods ending on or after December 31, 2004, all hospices, organ procurement organizations, rural health clinics, Federally qualified health centers, community mental health centers, and end-stage renal disease facilities must submit cost reports currently required under the Medicare regulations in a standardized electronic format. This rule also allows a delay or waiver of this requirement when implementation would result in financial hardship for a provider. The provisions of this rule allow for more accurate preparation and more efficient processing of cost reports.

**DATES:** *Effective Date:* The provisions of this final rule are effective September 22, 2003.

*Applicability Date:* The provisions of this final rule are effective for cost reporting periods ending on or after December 31, 2004.

**FOR FURTHER INFORMATION CONTACT:** Larry Stevenson, (410) 786–5529.

**SUPPLEMENTARY INFORMATION:** Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, PO Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 512–1800 or by faxing to (202) 512–2250. The cost for each copy is $10. As an alternative, you can view and photocopy the **Federal Register** document 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 website address is: *http://www.access.gpo.gov/nara/index.html.*

### I. Background

Generally, under the Medicare program, hospices, organ procurement organizations (OPOs), rural health clinics (RHCs), Federally qualified health centers (FQHCs), community mental health centers (CMHCs), and end-stage renal disease (ESRD) facilities are paid for the reasonable costs of the covered items and services they furnish to Medicare beneficiaries. Sections 1815(a) and 1833(e) of the Social Security Act (the Act) provided that no payments will be made to a provider unless it has furnished the information, requested by the Secretary of the Department of Health and Human Services (the Secretary), needed to determine the amount of payments due the provider. In general, providers submit this information through cost reports that cover a 12-month period. Rules governing the submission of cost reports are set forth in title 42 of the Code of Federal Regulations (CFR) 413.20 and 413. 24.

Under § 413.20(a), all providers participating in the Medicare program are required to maintain sufficient financial records and statistical data for proper determination of costs payable under the program. In addition, providers must use standardized definitions and follow accounting, statistical, and reporting practices that are widely accepted in the health care industry and related fields. Under § 413.20(b) and § 413.24(f), providers are required to submit cost reports annually, with the reporting period based on the provider's accounting year. Additionally, under § 412.52, all hospitals participating in the prospective payment system must meet cost reporting requirements set forth at § 413.20 and § 413.24.

Section 1886(f)(l)(B)(i) of the Act requires the Secretary to establish a standardized electronic cost reporting system for all hospitals participating in the Medicare program. This provision was effective for hospital cost reporting periods beginning on or after October 1, 1989. On January 2, 1997, we revised our regulations at § 413.24(f)(4)(ii) to extend the electronic cost reporting requirement to skilled nursing facilities (SNFs) and home health agencies (HHAs) (62 FR 26–31).

The required cost reports must be electronically transmitted to the intermediary in American Standard Code for Information Interchange (ASCII) format. In addition to the electronic file, hospitals, SNFs, and HHAs were initially required to submit a hard copy of the full cost report. We later revised our regulations in § 413.24(f)(4)(iv) to state that providers were required to submit, instead, a hard copy of a one-page settlement summary, a statement of certain worksheet totals found in the electronic file, and a statement signed by the provider's administrator or chief financial officer certifying the accuracy of the electronic file. In order to preserve the integrity of the electronic file, in the January 1997 final rule we specified procedures regarding the processing of the electronic cost report once it is submitted to the intermediary (62 FR 27).

### II. Provisions of the Proposed Regulations

With the exception of revising the first cost reporting period affected from those ending on or after December 31, 2002 to those ending on or after December 31, 2004, we have adopted the provisions as set forth in our proposed rule, published in the **Federal Register** on July 26, 2002 (67 FR 48840–48844). We revised the cost reporting periods affected to take into account the publication date for this final rule. We discuss the finalized provisions in section IV of this final rule.

### III. Analysis of and Responses to Public Comments

We received approximately 20 comments on the proposed electronic submission of cost reports requirements. These comments were from providers, professional organizations, trade associations, vendors and individuals. Summaries of the public comments

received and our responses to those comments are set forth below.

*Comment:* Several commenters requested that we add language to the regulation that would prohibit fiscal intermediaries (FIs) from requesting paper copies of the Medicare cost report, in addition to the electronic cost report.

*Response:* According to our CMS manual provisions (Provider Reimbursement Manual 15–2, chapter 1, sections 131 and 132), the electronic cost report file is considered the official cost report by the FI and, as a result, must be accepted by the FI. Since March 31, 1993, hospitals have not been required to submit a paper copy of the cost report to the FI . Similarly, since March 31, 2000, SNFs and HHAs have not been required to submit a paper copy of the cost report to the FI. We have, however, provided a two-year phase-in period for the providers that are subject to this regulation. During this two-year phase-in period, the paper copy of the cost report will be considered the official copy. After the expiration of the two-year period, though, a paper copy of the cost report will not be required to be submitted to the FI. We believe this phase-in period is necessary, so that providers are familiar with the requirements of electronic cost reporting.

*Comment:* We received several comments concerning our proposal to distribute free electronic cost reporting software to providers who can demonstrate that it would be a financial hardship to purchase software from vendors. One comment, from a software vendor, requested that we add language that would preclude the distribution of free software because it would be ''unfair'' to small vendors and the software would be poor quality. Another commenter asked that we specify a date that the free software would be available to providers. Also, we received a comment that the CMS-provided software would not allow providers to determine final settlement and that providers would still have to complete the cost report manually.

*Response:* With regard to the comment concerning adding language to the regulation that would preclude the distribution of free software, free software is made available to the providers based upon financial need only. The provider must demonstrate to the FI that the provider is financially unable to purchase commercial software. It has been our experience, with the hospitals, SNFs, and HHAs currently required to file electronically, that relatively few providers request the free software. If, however, the provider requests the free software and can demonstrate to the FI that it would be a financial hardship to purchase the software from a vendor, we will provide the software so that the provider can comply with the provisions of this rule. The quality of the software will be sufficient to allow the provider to comply with all provisions of this rule in a timely and efficient manner.

With regard to the comment concerning the projected date that the free software will be available, we expect that it should be available by September 30, 2004.

The comment that the CMS-provided software would not allow providers to determine final settlement and, as a result, that providers would still have to complete the cost report manually, is correct. The software allows the provider to create an electronic cost report file only for use by the FI and a final settlement amount is not necessary in this instance. Providers who use free software are always required to manually complete the cost report and to manually determine the final settlement.

*Comment:* We received a comment that the final regulation should also require that Comprehensive Outpatient Rehabilitation Facilities (CORFs) and Outpatient Physical Therapy providers (OPTs) file cost reports electronically.

*Response:* We are not requiring CORFs and OPTs to file electronically because CORFs are paid on a fee schedule for services furnished on or after April 1, 2001 and OPTs will be paid on a fee schedule for services furnished on or after July 1, 2003. For those providers with cost reporting periods beginning on or after the aforementioned dates, cost reports will no longer be required. We believe that it would be administratively burdensome as well as not economically feasible to require these providers to meet the electronic filing requirements for such a short period of time.

*Comment:* We received a comment that the final rule should include an exemption from the electronic filing requirement for no or low utilization providers because it appears that these providers are exempt from such filing requirements in § 413.24(h).

*Response:* Section 413.24(h) does not address the electronic filing requirement but it does provide that an FI may waive the requirement that a provider submit a full cost report if it qualifies as low utilization or no cost Medicare provider. Thus, based upon a waiver by the FI, under § 413.24(h), a low utilization or no Medicare utilization provider would not be required to file an electronic cost report. Because our current regulations clearly state that a full cost report need not be filed by a low utilization or no Medicare utilization provider, we believe that an exception, such as the one requested by the commenter, is not necessary for this final rule.

*Comment:* We received a comment that we should clarify the minimum requirements of what constitutes a financial hardship for the purposes of qualifying for the waiver and/or free software.

*Response:* Given the wide spectrum of the providers affected, we believe it is best to determine financial hardship on a case-by-case basis. Some examples of financial hardship include cash flow problems, previous year's net operating loss, and a required repayment of the past year's overpayment. These are some examples of financial hardship but should not be seen as all-encompassing. The flexibility to make these determinations is necessary as the providers differ greatly in terms of size, location, expenses, and services provided. The FI will need to have this flexibility in order to make a fair and reasonable determination for each provider.

*Comment:* We received several comments concerning the one-time pass through of costs (direct reimbursement on a dollar-for-dollar basis) for RHCs and FQHCs rather than reimbursing those providers based on the determination of the total allowable costs of the RHCs and FQHCs.

*Response:* We are unable to reimburse RHCs and FQHCs in a way other than direct reimbursement because to do so would require a statutory change in the method of reimbursement for the RHCs and FQHCs.

*Comment:* We received a comment reflecting concern that the cost of dial up Internet service required to file electronically would be a burden for rural providers.

*Response:* There is no requirement to use the Internet to electronically file a cost report. The medium for transfer of cost reports submitted electronically to FIs is a 3½″ diskette.

*Comment:* We received two comments expressing concern about the phase-in period. One concern was that the two-year phase-in period was too long. Another concern was that the two-year period should be extended to three years.

*Response:* We believe that the two-year phase-in period is necessary to allow providers to become familiar with the requirements of electronic filing and that a shorter phase-in period would be insufficient to accomplish this.

Similarly, prior experience with the hospital cost report, the SNF cost report,

and the HHA cost report indicate that the two-year phase-in period provides ample time for the providers to adjust to the electronic methods for filing the cost report, and a longer period is not necessary.

*Comment:* We received a comment that we should delay the implementation of the electronic filing requirement for FQHCs from December 31, 2002 until June 30, 2003 to allow those providers more time for implementation.

*Response:* We are revising the implementation date to December 31, 2004 to allow all providers more time to implement the rule.

*Comment:* We received a comment that recommended that we have a pilot testing period before implementing the electronic filing requirement.

*Response:* Electronic filing of cost reports has been required since March 31, 1993 for hospitals and for SNFs and HHAs since March 31, 2000 and, based on our experiences with hospitals, SNFs, and HHAs, we believe that the electronic filing requirements will be implemented by hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities, as efficiently as has been the case with the other providers mentioned. Moreover, the two-year phase-in period, which will end May 31, 2007, will allow sufficient time for the providers subject to this regulation to adapt to the electronic filing requirement. The hard copy of the cost report is the official copy during the two-year transition period. For this two-year phase-in period, no cost report will be rejected but the FIs will make the provider aware of the edits that the provider did not pass. This flexibility will allow the provider to correct any problems that the provider has encountered with electronic filing before the phase-in period ends.

*Comment:* We received a comment that a correction period of 60 days be allowed for providers to resubmit electronic cost reports that are rejected by the FI.

*Response:* While it is the responsibility of the provider to submit an acceptable cost report to the FI by the required due date of the cost report, we have established a two-year phase-in period where the hardcopy of the cost report will be the official cost report and will not be rejected by the FI—a concern of the commenter. The two-year phase-in period has been established to allow the provider sufficient time to familiarize itself with the electronic filing requirements. Also, during this two-year phase-in period, the FI will inform the provider concerning any problems that the provider may encounter with the electronic filing requirement that would cause rejection in the future. It should be noted, as well, that there already exists a 30-day period during which providers can correct errors and resubmit electronic cost reports to the FI (*See* Provider Reimbursement Manual 15–II, Chapter 1, section 140).

*Comment:* We received a comment that all current cost reports should be settled by the FIs before the implementation of the electronic filing requirement.

*Response:* The settlement of cost reports is not governed by this final rule and any changes regarding the settlement of cost reports are beyond the scope of this rule which is concerned solely with electronic filing requirements.

*Comment:* We received a comment that we should provide electronic Provider Statistical Reimbursement & Report data (PS&R)—reimbursement and statistical data that we prepare—to providers.

*Response:* Although this comment does not fall within the scope of this rule, we believe that it may be helpful to address this process issue. We note, therefore, that this information is used by the FI for the settlement of cost reports. The detailed PS&R, however, is available from the FI upon written request from the provider if there are any discrepancies between the provider's data and the PS&R summary report. The FI is required to send the summary PS&R report to the provider 30 days before the due date of the cost report.

*Comment:* A commenter requested that we not extend the ''complex'' and ''punitive'' criteria for acceptable cost reports currently imposed on hospitals, SNFS, and HHAs to the other providers affected by this final rule.

*Response:* We do not believe that acceptability criteria for electronic cost report filings are complex and they certainly are not intended to be punitive. We developed these criteria both to help the provider and to ensure that the provider is aware of what is required to file an acceptable cost report. We believe these criteria, which we attempt to keep at a minimum, will help ensure accuracy and save time to both the provider and the FI. Generally included in the criteria, for example, are the level one electronic edits that all cost reports must pass in order for the cost report to be acceptable. By clearly enumerating these level one edits in our criteria—the criteria most critical in the filing of an acceptable electronic cost report—we believe providers will have every opportunity to meet the requirements in a timely and accurate manner.

## IV. Provisions of the Final Rule

In this final rule, we are applying the current hospital, SNF, and HHA electronic cost reporting requirements to hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities with the exception that, for the first 2 years, the hard copy of the cost report must be submitted with the electronic cost report. Over that 2-year period (until May 31, 2007) the hard copy will continue to be the official copy. We believe that the use of electronically prepared cost reports will be beneficial for hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities because the cost reporting software for these reports will virtually eliminate computational errors and substantially reduce preparation time. Moreover, the use of cost reporting software will save time whenever the provider needs to change individual entries in a cost report.

This rule provides that a hospice, organ procurement organization, RHC, FQHC, CMHC, or ESRD facilities may submit a written request for a waiver or a delay of these requirements if it believes that implementation of the electronic submission requirement would cause a financial hardship. Consistent with the existing regulations (*see* § 413.24(h)), we are continuing to allow providers with low or no Medicare utilization to request a waiver of full or simplified cost reporting.

## V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA 1995), we are required to provide 30 days 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. However, the requirements referenced and discussed below are currently approved by OMB.

### *Section 413.24 Adequate Cost Data and Cost Finding*

Currently, § 413.24 requires hospitals, SNFs, and HHAs to submit electronic cost reports. However, as proposed in the regulation, hospices, OPOs, RHCs, FQHCs, CMHCs, or ESRD facilities will no longer have the option of submitting either a hard copy or electronic cost report. In addition to the electronic cost report, these providers will also continue to be required to submit to the appropriate FI, hard copies of a settlement summary, statement of certain worksheet totals, and the Federally prescribed statement signed

by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. We believe that these electronic filing requirements will initially increase the burden by approximately 40 hours and cost approximately $5000 for each cost reporting period. We expect that this burden will decrease as the providers become familiar and proficient in electronic filing.

However, as currently approved, these providers may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(ii) of this section if this requirement would cause a financial hardship.

As noted above, while all the above reporting requirements are subject to the PRA, they are currently approved under OMB approval numbers 0938–0050, ''Hospital/Healthcare Complex Cost Report,'' with a current expiration date of November 30, 2005, 0938–0463; ''Skilled Nursing Facility Cost Report,'' with a current expiration date of May 31, 2004; 0938–0022, ''Home Health Agency Cost Report,'' with a current expiration date of May 31, 2004; 0938–0758, ''Hospice Cost Report,'' with a current expiration date of March 31, 2005; 0938–0102, ''Organ Procurement Agency/Laboratory Statement of Reimbursable Costs,'' with a current expiration date of October 31, 2003, which is currently at OMB awaiting re-approval; 0938–0107, ''Independent Rural Health Clinic/Freestanding Federally Qualified Health Center Cost Report,'' with a current expiration date of October 31, 2005; 0938–0236, ''Medicare Independent Renal Dialysis Facility Cost Report,'' with a current expiration date of August 31, 2004; and 0938–0657, ''End Stage Renal Disease Network Cost Report,'' with a current expiration date of December 31, 2003, which is currently in the re-approval process.

**VI. Regulatory Impact Statement**

We have examined the impacts of this final 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 1955 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, when 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 annually). This rule will not have a significant economic impact on hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities, and, therefore, is not a major rule. There are no requirements for hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities to initiate new processes of care, and reporting; to increase the amount of time spent on providing or documenting patient care services; or to purchase computer software.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having annual receipts of $6 million to $29 million or less annually (*see* 65 FR 69432). For purposes of the RFA, all providers and small businesses that distribute cost-report software to providers are considered small entities. We do not believe that this rule will have a significant impact on these providers as no or low utilization providers already have the ability to file for a waiver of the electronic filing requirement. In demonstrated cases of financial hardship, however, we will provide free software. With computers so common in the work place today it is hard to imagine that a provider does not already access to a computer and, in the rare instance when a provider would have to purchase a computer, we believe the cost would be neglible. In addition, the providers have a period of almost two years to familiarize themselves with the electronic filing requirements, since the first cost reports will not be due until May 31, 2005. Our intermediaries are not considered small entities for the purposes of the RFA. Individuals and States are not included in the definition of small entities.

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.

We are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined, and we certify, that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

As stated above, under § 413.20(b) and § 413.24(f), providers are required to submit cost reports annually, with reporting periods based on the provider's accounting year. This final rule requires hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities, like hospitals, SNFs and HHAs, to submit their Medicare cost reports in a standardized electronic format. This requirement will take effect for cost reporting periods ending on or after December 31, 2004, meaning that the first electronic cost reports will be due May 31, 2005.

Currently, approximately 55 percent of all hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities submit a hard copy of an electronically prepared cost report to the intermediary. We believe that the provisions of this final rule will have little or no effect on these providers, except to reduce the time involved in copying and collating a hard copy of the report for intermediaries. Under this rule, instead of submitting a complete hard copy of the report, providers will be required to submit only hard copies of a settlement summary, statement of certain worksheet totals, and a statement signed by the administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. In addition to the 55 percent of providers that currently use electronic cost reporting, this rule will not affect those providers that do not file a full cost report and, as stated above, would not be required to submit cost reports electronically.

This rule may have an impact on those providers who do not prepare electronic cost reports, some of whom may have to purchase computer equipment, obtain the necessary software, and train staff to use the software. However, as discussed below, we believe that the potential impact of this final rule on those providers who do not prepare electronic cost reports will be insignificant.

First, a small number of the 45 percent of providers that do not submit electronic cost reports may have to purchase computer equipment to comply with the provisions of this rule. These providers are generally owned

and operated by one or two individuals and are often located in rural areas. They include approximately 1,500 RHCs and 1,500 FQHCs. We estimate that 1,350 of the 3000 RHCs and FQHCs may not have the necessary computer equipment. We believe, however, that most providers already have access to computer equipment, which they are now using for internal record keeping purposes, as well as for submitting electronically generated bills to their fiscal intermediaries, for example. Thus, we do not believe that obtaining computer equipment will be a major obstacle to electronic cost reporting for most providers. For those providers that may have to purchase computer equipment, we note that, in accordance with current regulations governing payment of provider costs, we will pay for the cost of the equipment as an overhead cost. Rural health clinics and FQHCs will be reimbursed subject to a payment limit; OPOs reimbursed based on costs; hospices reimbursed according to fee schedule; ESRDs paid a composite rate, and CMHCs will be reimbursed through a blend of prospective payment (PPS) and cost.

We recognize that a potential cost for providers that do not submit electronic cost reports will be that of training staff to use the software. Since most hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities currently use computers, we do not believe that training staff to use the new software will impose a large burden on providers. An additional cost would be the cost of the software offered by commercial vendors. However, providers could eliminate this cost by obtaining the necessary software from us, free of charge. In those instances when these requirements may cause hardship, a waiver can be granted.

The requirement that hospitals submit cost reports in a standardized electronic format has been in place since October 1989. Since that time, the accuracy of cost reports has increased and we have received very few requests for waivers. Additionally, we have not received any comments from the hospital industry indicating that the use of electronic cost reporting is overly burdensome. We believe that electronic cost reporting will be equally effective for hospices, OPOs, RHCs, FQHCs, CMHCs, and ESRD facilities, with the benefits (such as increased accuracy and decreased preparation time) outweighing the costs of implementation for most providers.

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 one year by State, local, or tribal governments, in the aggregate, or by the private sector, that exceeds the inflation-adjusted threshold of $110 million. This rule does not impose any costs that would exceed the $110 million threshold on the governments mentioned, or the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have examined this final rule and have determined that this rule will not have an impact on the rights, roles, and responsibilities of State, local, or tribal governments.

In accordance with the provisions of Executive Order 12866, this final rule was reviewed by the Office of Management and Budget.

**List of Subjects in 42 CFR Part 413**

Health facilities, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid amends 42 CFR chapter IV part 413 as follows:

## PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES

■ 1. The authority citation for part 413 continues to read as follows:

**Authority:** Secs. 1102, 1812(d), 1814(b), 1815, 1833(a), (i) and (n), 1861(v), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395x(v), 1395hh, 1395rr, 1395tt, and 1395ww).

■ 2. Section 413.24 is amended by revising existing paragraphs (f)(4)(i) through (f)(4)(v) to read as follows:

**§ 413.24 Adequate cost data and cost finding.**

* * * * *

(f) *Cost reports.* * * *

(4) *Electronic submission of cost reports.*

(i) As used in this paragraph, ''provider'' means a hospital, skilled nursing facility, home health agency, hospice, organ procurement organization, rural health clinic, Federally qualified health clinic, community mental health center, or end-stage renal disease facility.

(ii) Effective for cost reporting periods beginning on or after October 1, 1989 for hospitals, cost reporting periods ending on or after December 31, 1996 for skilled nursing facilities and home health agencies, and cost reporting periods ending on or after December 31, 2004 for hospices, organ procurement organizations, rural health clinics, Federally qualified health centers, community mental health centers, and end-stage renal disease facilities, a provider is required to submit cost reports in a standardized electronic format. The provider's electronic program must be capable of producing the CMS standardized output file in a form that can be read by the fiscal intermediary's automated system. This electronic file, which must contain the input data required to complete the cost report and to pass specified edits, must be forwarded to the fiscal intermediary for processing through its system.

(iii) The fiscal intermediary stores the provider's as-filed electronic cost report and may not alter that file for any reason. The fiscal intermediary makes a ''working copy'' of the as-filed electronic cost report to be used, as necessary, throughout the settlement process (that is, desk review, processing audit adjustments, and final settlement). The provider's electronic program must be able to disclose if any changes have been made to the as-filed electronic cost report after acceptance by the intermediary. If the as-filed electronic cost report does not pass all specified edits, the fiscal intermediary must return it to the provider for correction. For purposes of the requirements in paragraph (f)(2) of this section concerning due dates, an electronic cost report is not considered to be filed until it is accepted by the intermediary.

(iv) Effective for cost reporting periods ending on or after September 30, 1994 for hospitals, cost reporting periods ending on or after December 31, 1996 for skilled nursing facilities and home health agencies, and cost reporting periods ending on or after December 31, 2004 for hospices, organ procurement organizations, rural health clinics, Federally qualified health centers, community mental health centers, and end-stage renal disease facilities, a provider must submit a hard copy of a settlement summary, a statement of certain worksheet totals found within the electronic file, and a statement signed by its administrator or chief financial officer certifying the accuracy of the electronic file or the manually prepared cost report. During a transition period (first two cost-reporting periods on or after December 31, 2004), hospices, organ procurement

organizations, rural health clinics, Federally qualified health centers, community mental health centers, and end-stage renal disease facilities must submit a hard copy of the completed cost report forms in addition to the electronic file. The following statement must immediately precede the dated signature of the provider's administrator or chief financial officer:

I hereby certify that I have read the above certification statement and that I have examined the accompanying electronically filed or manually submitted cost report and the Balance Sheet Statement of Revenue and Expenses prepared by_____(Provider Name(s) and Number(s)) for the cost reporting period beginning _____ and ending _____ and that to the best of my knowledge and belief, this report and statement are true, correct, complete and prepared from the books and records of the provider in accordance with applicable instructions, except as noted. I further certify that I am familiar with the laws and regulations regarding the provision of health care services, and that the services identified in this cost report were provided in compliance with such laws and regulations.

(v) A provider may request a delay or waiver of the electronic submission requirement in paragraph (f)(4)(ii) of this section if this requirement would cause a financial hardship or if the provider qualifies as a low or no Medicare utilization provider. The provider must submit a written request for delay or waiver with necessary supporting documentation to its intermediary no later than 30 days after the end of its cost reporting period. The intermediary reviews the request and forwards it, with a recommendation for approval or denial, to CMS central office within 30 days of receipt of the request. CMS central office either approves or denies the request and notifies the intermediary within 60 days of receipt of the request.

* * * * *

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

Dated: February 21, 2003.

**Thomas A. Scully,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: April 24, 2003.

**Tommy G. Thompson,**

*Secretary.*

[FR Doc. 03–21441 Filed 8–21–03; 8:45 am]

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Centers for Medicare & Medicaid Services**

**Centers for Disease Control and Prevention**

**42 CFR Part 493**

**[CMS–2226–CN]**

**RIN 0938–AK24**

## Medicare, Medicaid, and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications; Correction

**AGENCY:** Centers for Disease Control and Prevention (CDC) and Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Final rule; correction.

**SUMMARY:** This document corrects technical errors that appeared in the final rule published in the **Federal Register** on January 24, 2003, entitled ''Medicare, Medicaid and CLIA Programs; Laboratory Requirements Relating to Quality Systems and Certain Personnel Qualifications.'' This document is a supplement to the January 24, 2003 final rule.

**EFFECTIVE DATE:** September 22, 2003.

**FOR FURTHER INFORMATION CONTACT:** Rhonda S. Whalen (CDC), (770) 488–8155.

Judith A. Yost (CMS), (410) 786–3531.

**SUPPLEMENTARY INFORMATION:**

### I. Background

In FR Doc. 03–1230 of January 24, 2003 (68 FR 3640), there were several technical errors that are identified and corrected in the ''Correction of Errors'' section below. The corrections described below are effective September 22, 2003.

Specifically, this document corrects errors of omission, clarifies ambiguities, and corrects erroneous references and typographical errors. We would ordinarily publish these changes in a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. This notice and comment rulemaking procedure can be waived, however, if an agency finds good cause to do so (that is, notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest) and it incorporates a statement of the finding and its reasons therefore in the final rule. We find good cause to waive notice and comment procedures for the corrections contained in this final rule for the reasons set forth in section III of this notice.

### II. Correction of Errors

*A. Preamble Corrections*

■ In the final rule published on January 24, 2003 (68 FR 3640), make the following corrections:

■ On page 3641, in column three, in line seven from the bottom of the page, ''Establish'' is corrected to read ''establish''.

■ On page 3642, in column two, in the first paragraph carried over from column one, in lines 13 and 14, the words ''the National Registry for Clinical Chemistry'' are corrected to read ''the National Registry of Certified Chemists (formerly known as the National Registry in Clinical Chemistry)''.

■ On page 3643, in column two of the Table, in lines 18, 21, and 24, ''systems'' is corrected to read ''system''.

■ On page 3648, in column three of the Table, in line 14, ''§§ 493.1274(e)(1)(i) through (e)(1)(v), and (e)(2)'' is corrected to read ''§§ 493.1274(e)(1)(i) through (e)(1)(iii), and (e)(2)''.

■ On page 3650, in column two of the Table, in lines 2, 4, 5, 7, 9, 10, 12, 13, 14, 15, 16, 17, 19, 20, 22, 23, 24, 25, 28, 32, 38, 40, 42, 44, 45, 46, 47, 48, and 50 (twice), add the word ''quality'' before ''assessment''.

■ On page 3650, in column three of the Table, in line 18, ''§§ 493.1230; 493.1236(a)(1); 493.1239(a) and (b)'' is corrected to read ''§§ 493.1230; 493.1236(a); 493.1239(a) and (b)''.

■ On page 3671, in column two, in the first paragraph of the response, ''the American Board of Medical Immunology'' is corrected to read ''the American Board of Medical Laboratory Immunology.''

■ On page 3671, in column two, in the first paragraph of the response, ''the National Registry for Clinical Chemistry'' is corrected to read ''the National Registry of Certified Chemists (formerly known as the National Registry in Clinical Chemistry)''.

■ On page 3673, in column three, in the first paragraph of the response, in line 16, ''quality systems include'' is corrected to read ''a quality system includes''.

■ On page 3674, in column two, in Subpart A—General Provisions (Definitions), in the first bullet point under that heading, add the words ''nonwaived test'' and ''waived test'' in alphabetical order.

■ On page 3674, in column two, in Subpart A—General Provisions (Definitions), add, above the third bullet, a new bullet with the words ''We revised