

- a. Revising paragraph (d) introductory paragraph;
- b. Revising paragraph (e)(10) introductory text; and
- c. Revising paragraph (e)(11).
The revisions read as follows:

§ 63.864 Monitoring requirements.

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(d) *Continuous opacity monitoring system (COMS)*. The owner or operator of each affected kraft or soda recovery furnace or lime kiln equipped with an ESP must install, calibrate, maintain, and operate a COMS according to the provisions in §§ 63.6(h) and 63.8 and paragraphs (d)(1) through (4) of this section.

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(e) * * *

(10) The owner or operator of each affected kraft or soda recovery furnace,

kraft or soda lime kiln, sulfite combustion unit, or kraft or soda smelt dissolving tank equipped with a wet scrubber must install, calibrate, maintain, and operate a CPMS that can be used to determine and record the pressure drop across the scrubber and the scrubbing liquid flow rate at least once every successive 15-minute period using the procedures in § 63.8(c), as well as the procedures in paragraphs (e)(10)(i) and (ii) of this section:

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(11) The owner or operator of each affected semichemical combustion unit equipped with an RTO must install, calibrate, maintain, and operate a CPMS that can be used to determine and record the operating temperature of the RTO at least once every successive 15-minute period using the procedures in

§ 63.8(c). The monitor must compute and record the operating temperature at the point of incineration of effluent gases that are emitted using a temperature monitor accurate to within ±1 percent of the temperature being measured.

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■ 4. Section 63.865 is amended by revising paragraph (a)(1) to read as follows:

§ 63.865 Performance test requirements and test methods.

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(a) * * *

(1) Determine the overall PM emission limit for the chemical recovery system at the mill using Equation 1 of this section as follows:

$$EL_{PM} = \frac{[(C_{ref,RF})(Q_{RFtot}) + (C_{ref,LK})(Q_{LKtot})](F1)}{(BLS_{tot})} + ER1_{ref,SDT} \quad (\text{Eq. 1})$$

Where:

EL_{PM} = overall PM emission limit for all existing process units in the chemical recovery system at the kraft or soda pulp mill, kg/Mg (lb/ton) of black liquor solids fired.

$C_{ref,RF}$ = reference concentration of 0.10 g/dscm (0.044 gr/dscf) corrected to 8 percent oxygen for existing kraft or soda recovery furnaces.

Q_{RFtot} = sum of the average volumetric gas flow rates measured during the performance test and corrected to 8 percent oxygen for all existing recovery furnaces in the chemical recovery system at the kraft or soda pulp mill, dry standard cubic meters per minute (dscm/min) (dry standard cubic feet per minute (dscf/min)).

$C_{ref,LK}$ = reference concentration of 0.15 g/dscm (0.064 gr/dscf) corrected to 10 percent oxygen for existing kraft or soda lime kilns.

Q_{LKtot} = sum of the average volumetric gas flow rates measured during the performance test and corrected to 10 percent oxygen for all existing lime kilns in the chemical recovery system at the kraft or soda pulp mill, dscm/min (dscf/min).

F1 = conversion factor, 1.44 minutes·kilogram/day·gram (min·kg/d·g) (0.206 minutes·pound/day·grain (min·b/d·gr)).

BLS_{tot} = sum of the average black liquor solids firing rates of all existing recovery furnaces in the chemical recovery system at the kraft or soda pulp mill measured during the

performance test, megagrams per day (Mg/d) (tons per day (ton/d)) of black liquor solids fired.

$ER1_{ref,SDT}$ = reference emission rate of 0.10 kg/Mg (0.20 lb/ton) of black liquor solids fired for existing kraft or soda smelt dissolving tanks.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 476, and 484

[CMS-3055-F]

RIN 0938-AK68

Medicare Program; Photocopying Reimbursement Methodology

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

ACTION: Final rule.

SUMMARY: This final rule increases the rate of reimbursement for expenses incurred by prospective payment system (PPS) hospitals for photocopying medical records requested by Quality Improvement Organizations (QIOs), formerly known as Utilization and Quality Control Peer Review Organizations (PROs). We are increasing the rate from 7 cents per page to 12

cents per page to reflect inflationary changes in the labor and supply cost components of the formula.

This final rule also provides for the periodic review and adjustment of the per-page reimbursement rate to account for inflation and changes in technology. The methodology for calculating the per-page reimbursement rate will remain unchanged.

We are also providing for the payment of the expenses of furnishing photocopies to QIOs, to other providers subject to a PPS (for example, skilled nursing facilities and home health agencies), in accordance with the rules established for reimbursing PPS hospitals for these expenses.

EFFECTIVE DATE: These regulations are effective on January 5, 2004.

FOR FURTHER INFORMATION CONTACT: Les Caplan, (410) 786-7223.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1866(a)(1)(F) of the Social Security Act (the Act) requires a hospital, as a condition of Medicare participation, to enter into an agreement with a quality improvement organization (QIO), for the peer review of Medicare services provided by the hospital. (Note: QIOs were formerly known as peer review organizations (PROs). We published a final rule with comment period on May 24, 2002 (67 FR 36539), changing the name to QIOs.) Our regulations at 42 CFR 476.78 provide that health care facilities that

submit Medicare claims must cooperate in the conduct of QIO reviews, including providing the QIO with information necessary to its determinations. This often includes providing the QIO with photocopies of patients' medical records.

We published a final rule on October 20, 1992, in the **Federal Register** (57 FR 47779), following notice-and-comment rulemaking, which established a formula for calculating the rate of reimbursement for these photocopy costs incurred by hospitals. Using this formula, we set the rate at 7 cents per page. The regulation requires us to determine a fixed payment amount per page by adding per-page labor costs and per-page supply costs. The regulation also provides for Medicare payment for the costs of first class postage for mailing records to QIOs. As discussed in detail in the October 20, 1992, final rule (57 FR 47779), the payment established by § 476.78 represents an additional payment to hospitals under the prospective payment system (PPS) for photocopy costs. Payment for the equipment and overhead costs associated with furnishing the QIO with required documentation is made under other Medicare payment provisions for capital-related costs and inpatient operating costs.

The formula for calculating the per-page reimbursement rate for photocopies is set forth at § 476.78(c), which provides:

Photocopying reimbursement methodology for prospective payment system hospitals. Hospitals subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the hospitals' responsibility to the QIOs to provide photocopies of requested hospital records. The payment is in addition to payment already provided for these costs under other provisions of the Social Security Act and is based on a fixed amount per page as determined by CMS as follows:

(1) *Step one.* CMS adds the annual salary of a photocopy machine operator and the costs of fringe benefits as determined in accordance with the principles set forth in OMB circular A-76.

(2) *Step two.* CMS divides the amount determined in paragraph (c)(1) of this section by the number of pages that can be reasonably expected to be made annually by the photocopy machine operator to establish the labor cost per page.

(3) CMS adds to the per-page labor cost determined in paragraph (c)(2) of this section the per-page costs of supplies.

Using this formula we established the per-page rate of 7 cents in the October 20, 1992, final rule. The validity of this rule and its reimbursement methodology were challenged in a certified class action by Medicare—participating hospitals, in the U.S. Court of Appeals for the Ninth Circuit. *Queen of Angels/Hollywood Presbyterian Medical Center v. Shalala*, 65 F.3d 1472, 1476 (9th Cir. 1995). The Court of Appeals upheld the validity of our photocopy reimbursement methodology and sustained the lawfulness of the 7 cents per page rate established in the rule.

Due to increases in labor and supply costs, we are increasing the reimbursement rate from 7 cents per page to 12 cents per page in accordance with the established court-approved methodology set forth in § 476.78(c).

Current Photocopy Reimbursement Rate

Under the current regulation, we apply a uniform per-page rate on a nationwide basis to all PPS hospitals that have QIO agreements. We base the calculation on labor and supply costs. The calculation in the current rule, as discussed in the preamble to the October 20, 1992, rule, is based on the following:

- An operator will copy approximately 364,320 pages annually.
 - The salary level of an operator is equivalent to a GS-5 experienced midlevel secretary (\$17,686) plus 27.9 percent fringe benefits (\$4,934) for a total salary of \$22,620.
 - Paper costs are 0.5 cents per page (\$25 per case of paper with 5,000 sheets in a case).
 - Toner and developer costs are 0.5 cents per page.
- The total cost per page is 7 cents.

II. Provisions of the Proposed Regulations

On November 22, 2002, we published a proposed rule (67 FR 70358) in which we proposed to increase the rate of QIO-related photocopy reimbursement from 7 cents to 12 cents per page. We calculated this rate by updating the salary, fringe benefits, and supply figures used in the October 20, 1992, final rule. In accordance with the methodology at § 476.78(c), we considered the following factors in calculating the proposed rate: (1) The labor costs associated with photocopying and (2) the costs of supplies.

A. Labor Costs

Labor costs were calculated consistent with the methodology at § 476.78(c), first, by adding the annual salary of a

photocopy machine operator with the costs of fringe benefits, and second, by dividing that sum by the number of pages that can reasonably be expected to be made in a year.

B. Annual Salary of a Photocopy Machine Operator

In the October 20, 1992, rule, we adopted the salary level for an experienced (GS-5) midlevel secretary in the Federal government as representative of that of a photocopy machine operator. Use of this figure approximated or exceeded the actual salary information for individuals performing these tasks that had been submitted by various commenters. Furthermore, we determined that use of this salary level yielded payments that were more than adequate to ensure a sufficient skill level. The annual salary of \$17,686 used in the October 20, 1992, rule was derived from the U.S. Office of Personnel Management's 1992 General Schedule.

In this final rule, we will continue to deem the salary of a Federal GS-5 midlevel secretary as representative of a photocopy operator's salary; however, we will update the figure to take into account increases in the payment rate of a midlevel secretary. Thus, as discussed in the proposed rule, we are using the GS-5 annual salary of \$28,727 derived from the U.S. Office of Personnel Management's 2002 General Schedule to calculate the revised rate.

C. Fringe Benefits

In the October 20, 1992, final rule, we ascribed the fringe benefits of an employee to be 27.9 percent of the employee's salary, which was the standard percentage dictated by the cost principles set forth in the Office of Management and Budget (OMB) Circular A-76. While there may be other yardsticks to measure this component of costs, we find this to be a reasonable resource since the thrust of this OMB circular is to help the government compare potentially incurred costs to determine whether the costs can be more economically incurred internally or through contract with a commercial source. Therefore, we continue to use OMB Circular A-76 to calculate the annual fringe benefit cost. Accordingly, fringe benefits were calculated in the November 22, 2002, proposed rule based on 29.7 percent of the GS-5 salary as outlined in the OMB Circular A-76 Transmittal Memorandum 19—FY 2000 estimate. Thus, the annual fringe benefit cost is \$8,532 (\$28,727 * 29.7 percent).

D. Number of Pages Copied Annually

In this final rule, we are using 364,320 pages per year in the calculation of the annual labor cost. In the October 20, 1992, rule, we determined that 364,320 was the number of pages that could reasonably be expected to be copied in a year. Earlier, in the proposed rule "Changes to Peer Review Organizations Regulations", published on March 16, 1988, at 53 FR 8654, we had proposed the use of 748,000 pages per year in the calculation of the annual labor cost. This initial figure was determined based on copying documents at a rate of six pages per minute for each hour in an 8 hour day, 5 days a week, 52 weeks per year. The estimate was based on hand feeding of documents into the photocopying machine for duplication, although we recognized that there are many photocopying tasks that may be accomplished through automatic feeds. Automatic feeds greatly increase the number of pages that can be generated by a machine on an hourly basis, and as a result, greatly decrease the cost of photocopying per page.

In response to comments received on the March 16, 1988, proposed rule (53 FR 8654), we revised the 748,000 figure in the October 20, 1992, final rule to account for time spent by the photocopy machine operator in search and retrieval tasks, and time away from work on annual vacation, sick, and holiday leave. This resulted in a reduction from 748,000 to 364,320 in our estimate of the number of pages that may be reasonably expected to be made annually, and a corresponding increase in the per-page labor rate.

We are unaware of any significant changes in technology since the October 20, 1992, final rule (57 FR 47779) that would lead to either a significant decrease or increase in the annual number of pages that may be copied. Nor are we aware of any changes that would significantly increase or decrease the time allocated to search and retrieval tasks. Therefore, we continue to use the 364,320 figure to calculate the per-page labor cost.

E. Calculation of Per-Page Labor Costs

To determine the per-page labor cost, the total of salary (\$28,727) and fringe benefits (\$8,532) costs, which amount to \$37,259, was divided by 364,320 pages, the number of copies made in a year, resulting in an annual labor cost per page of 10 cents (\$37,259/364,320 pages).

F. Supply Costs

In the proposed rule, we proposed a total supply cost of 2.3 cents per page.

This is based on a per-page paper cost of 0.5 cents and a developer and toner cartridge cost of 1.8 cents per page. The paper costs were calculated based on \$23 per case of paper with 5,000 sheets in a case. This equates to 0.5 cents per page (\$23/5,000).

In this rule, we used an objective methodology to calculate the per-page cost for toner and developer that can also be used in future updates. We calculated these costs using estimates of the costs for toner cartridges and developer drums contained in the General Services Administration (GSA) supply catalogue, and on the basis of a photocopy machine producing 364,320 pages annually.

G. Payment Rate Per Page

Consistent with § 476.78(c)(3), the payment rate per page is the total of the per-page labor cost and the per-page supply cost, which is equivalent to 12 cents. The established calculation methodology actually results in a cost of 12.3 cents per page, however, consistent with our policy and generally accepted mathematics principles, we chose to round down to 12 cents. We believe this decision is both reasonable and supportable, based on the fact that the higher amount substantially exceeds all published OMB inflation indexes, including the Consumer Price Index (CPI)-Wage index (photocopying expense is largely comprised of labor costs).

H. Future Updates to Rate of Photocopy Reimbursement

In addition to updating the rate of reimbursement for photocopies, we are also amending the existing regulation to permit the rate to be adjusted without undergoing notice-and-comment rulemaking each time it needs to be adjusted to reflect inflationary or technology changes.

We intend to review and adjust the rate periodically in accordance with the same factors considered in establishing the rate in the October 20, 1992, final rule and the updated rate in this final rule. This review will include an examination of the labor and supply components of the formula, and we will update the rate as necessary to account for significant inflationary changes to these components.

Absent some compelling reason, in future updates, we will continue to deem the salary and fringe benefits of a Federal government GS-5 midlevel secretary as representative of the salary and fringe benefits of a photocopy machine operator and use those values to calculate the reimbursement rate. Also, absent some compelling reason or

major technological change that would lead to a significant increase or decrease in the number of pages that can be made annually, we will not change the number of pages used in calculating the rate.

I. Reimbursement to Other PPS Providers of the Cost of Photocopying

We will provide for the payment of the expenses of furnishing photocopies to QIOs, to other providers subject to a PPS (for example, skilled nursing facilities (SNFs) and home health agencies (HHAs)), in accordance with the rules established at § 476.78 for reimbursing PPS hospitals for these expenses.

Current regulations do not address reimbursement for providers other than hospitals for costs of photocopying medical records in cooperation with QIO review activities because in the past QIO review of providers other than hospitals was relatively insignificant. To the extent that this review activity took place, it was minimal, and the related costs were included on the provider's cost report. SNFs, HHAs, and other providers have recently converted from the cost-based reimbursement system to a PPS. Because QIO review of these providers has been minimal or nonexistent, costs related to this activity are not adequately reflected in the base PPS rate. Therefore, we believe it is appropriate to provide for a means of paying for these costs when they occur. To accomplish this change, we will replace the more narrow term "hospitals" with "providers," in § 476.78(b)(2) and (c), to include other providers subject to a PPS.

Additionally, we will revise the payment provisions for SNFs and HHAs by adding a paragraph at § 413.355 and § 484.265, that authorizes reimbursement for the costs of photocopying and mailing medical records required for QIO review, to SNFs and HHAs.

We will amend § 476.78(d) to provide that, as with other disputes regarding Medicare payment to providers, disputes concerning payments for costs related to QIO review under § 476.78 and the other payment provisions of the Medicare statute and regulations must be presented in accordance with the administrative and judicial review requirements of section 1878 of the Act and subpart R of 42 CFR part 405.

III. Analysis of and Responses to Public Comments

We received three timely items of correspondence in response to the proposed rule published on November 22, 2002. A summary of the major issues

raised in those comments and our responses follow:

Comment: One QIO commented that the November 22, 2002, proposed rule would increase pass-through photocopy costs well beyond the amount budgeted in their seventh round Medicare contract. This increase could cause the QIO to exceed the total cost of its contract.

Response: Increased photocopying costs are included in the seventh round scope of work funding level. However, these costs are a true pass-through; that is, CMS is responsible for paying providers, and CMS uses its QIO contractors as the vehicle to pay them. Although CMS does not anticipate increasing the total cost of each QIO contract immediately upon publication of this rule, any time a QIO believes it will exceed the total cost of its contract, the QIO should immediately notify CMS (see "Limitation of Cost" clause in the seventh round contract). If the excess costs are the result of increased photocopying reimbursement, CMS will exercise one of the four options CMS always uses in similar cases—we will either request that money be added to the contract, reduce work, ask the QIO to move funds between cost centers or line items, or some combination of these options. In no case will CMS expect the QIO to absorb any excess pass-through with existing contract funds without a corresponding reduction or shifting in level of effort.

Comment: One hospital commented that the method for calculating labor costs described in section II.A of the preamble of the November 22, 2002, proposed rule only provides for the cost of a photocopy machine operator, while in actual practice a significant portion of records reproduction time should be attributed to record retrieval, review, and re-filing by a records technician. The hospital further stated its pay scale for a records technician ranges from \$8.30 to \$11.22 per hour.

Response: We agree with this comment. However, in section II.D of the preamble of the November 22, 2002, proposed rule, we explained how we calculated the estimated number of pages copied annually. As discussed in detail at 57 FR 47780, this estimate was adjusted before publication of the current regulation to take into account the appropriate amount of labor time required to perform all of the steps that are performed in addition to the actual photocopying, such as logging in the request, retrieving the record, re-filing the record, and mailing copies. Thus, the term "photocopy machine operator" can reasonably be interpreted to include records technicians or anyone else

directly involved in the hands-on process. Further, section II.B of the preamble of the November 22, 2002, proposed rule explains that we used an updated representative annual salary of \$28,727, or an hourly rate of \$13.81, which exceeds this provider's salary range for a records technician. Therefore, we have not increased the per-page reimbursement rate based on this comment.

Comment: Another commenter questioned the raw data we applied to the approved methodology for calculating the per-page cost of photocopying medical records. Although this commenter strongly supported the three primary objectives of the rule (to increase reimbursement, extend provisions of the rule to all PPS providers, and allow for periodic adjustment of rates without notice and comment rulemaking), the commenter contended the rate should be significantly higher than the proposed 12 cents per page.

In particular, this organization stated the proposed labor rate is insufficient to retain qualified personnel in the private sector, fringe benefit rates are too low, the number of pages copied annually is too high due to recent Health Insurance Portability and Accountability Act of 1996 (HIPAA) requirements, and the cost of supplies is too low as a result of comparing GSA bulk purchase costs to actual costs available to private sector companies. The commenter believes we used the October 20, 1992, regulation as a starting point for current calculations and that regulation was based on artificially low cost assumptions.

The commenter supports extending the proposed reimbursement methodology to non-hospital PPS providers and also supported the periodic review provisions. However, the commenter asked us to amend the rate review section to require such a review at no more than 5-year intervals.

Response: In this rule, we used recent cost data to calculate the proposed per-page photocopy costs and did not simply build on 1992 data. However, we believe that the data used in both this rule and the 1992 rule is reasonable and accurately reflects the costs associated with this responsibility. Further, we believe the proposed representative salary and fringe benefit rates of \$28,727 and 29.7 percent, respectively, are reasonable and sufficient to attract and retain qualified personnel. The fringe benefit (F/B) rate, in particular, is very close to the mean F/B rate of the numerous contractors we reviewed before publication of the November 22, 2002, proposed rule, to validate the A-76 Transmittal Memorandum. Although

the 29.7 percent F/B rate is based on the 2000 OMB guidance, we have applied it to a higher base figure and see no reason to adjust it further. The \$28,727 salary estimate represents a mid-level GS-5 secretary salary in 2002, which we believe is a fair and accurate comparison to the skill level necessary to process medical record photocopying requests.

The estimated number of pages has remained constant since the October 20, 1992, regulation was published. Although the commenter may be correct that HIPAA privacy requirements will modestly reduce the maximum number of pages an operator or technician can copy per year, it is still too soon to calculate the exact effect of that legislation. Further, we believe that increases in the speed and simplicity of reproduction hardware over the last 10 years may offset any decreases in volume resulting from HIPAA.

The comment that the cost of supplies to non-governmental organizations exceeds the GSA catalogue price may be valid. However, the GSA price provides a solid benchmark that does not vary widely by vendor or product quality. Further, our proposed overall reimbursement rate per page amounts to a 7 percent annual increase over the 10 years since publication of the previous rule. This is approximately twice the inflation index rate and adequately compensates for any modest differences between the government and private-sector costs of supplies.

We believe the suggestion to include a maximum 5-year interval between review periods has some merit but may be unnecessary. By eliminating the need for notice and comment rulemaking, it becomes unlikely that any future rate adjustment will take longer than 5 years and potentially could be more frequent.

IV. Provisions of the Final Regulations

This final rule incorporates the provisions of the proposed rule with only one minor change. We have deleted the proposed revision of § 476.78(b)(4), thus leaving that section unchanged from the existing text. The proposed amendment, replacing "hospital" with "provider," had an unintended consequence of appearing to extend the requirement to provide QIOs with discharge notices from hospitals to other inpatient providers. That is neither the purpose nor the intent of this final rule.

V. Collection of Information Requirements

Under the Paperwork Reduction Act (PRA) of 1995, agencies are required to provide 60-day notice in the **Federal**

Register and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- Whether the information collection is necessary and useful to carry out the proper functions of the agency;
- The accuracy of the agency's estimate of the information collection burden;
- The quality, utility, and clarity of the information to be collected; and
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Section 476.78 of this regulation contains information collection requirements. In summary, § 476.78 requires providers to submit information to the QIO during the conduct of a QIO review. Because this information is collected during the conduct of an audit, investigation, and/or an administrative action, we believe these collection requirements are not subject to the PRA as stipulated under 5 CFR 1320.4.

VI. Regulatory 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.

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 rules that constitute significant regulatory action, including rules that have an economic effect of \$100 million or more annually. This final rule is not a major rule in terms of the aggregate costs involved.

The 53 separate QIO contracts are awarded on a staggered 3-year basis. Current sixth scope of work contracts provide photocopy reimbursement costs of 7 cents per page. The total dollars budgeted were \$8.6 million per year and

the 3-year costs were \$25.9 million. We estimate by the time this final regulation is published, 19 QIOs will have completed their sixth round contracts, and the other 34 will have less than 153 months (combined) out of a total of 636 months (for all 53 QIOs) remaining in the final year of their sixth round contracts. This translates to 24 percent of the final sixth round year. As such, we project this regulation will increase the costs in the last (that is, current) year of the sixth scope of work by \$1.5 million above the previous budgeted level of \$8.6 million, to a total of \$10.1 million. However, in future years—based on the full 12 months and all 53 QIOs under contract—the increase will be nearly \$6.2 million annually.

Thus, we have determined that this final rule is not a major rule with economically significant effects because it will not result in increases in total expenditures of \$100 million or more per year.

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 small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million or less annually (see 65 FR 69432). Individuals and States are not included in the definition of a small entity.

We generally prepare a regulatory flexibility analysis that is consistent with the RFA unless we certify that a rule will not have a significant impact on a substantial number of small entities. We have not prepared an analysis for the RFA because we have determined, and certify, that this final rule will have no significant economic impact on small entities. The regulation will not impose any economic or operational regulatory burdens on small entities. The regulation will only assist providers in performing the tasks required under the QIO program sixth scope of work, by increasing the reimbursement for providing copies of documents to the QIOs.

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 have not prepared an analysis for section 1102(b) of the Act because

we have determined that this final regulation will not have a significant impact on the operations of small rural hospitals for the reasons stated above in our discussion of the RFA.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in an expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million or more. We have determined that this final rule will not result in such an expenditure. Rather, the final rule will benefit providers by increasing the photocopy reimbursement rate.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a rule that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this final rule under the threshold criteria of Executive Order 13132 and have determined that it will not have a substantial direct effect on the rights, roles, and responsibilities of States or local governments.

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

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

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

42 CFR Part 476

Grant programs—health, Health care, Health facilities, Health professions, Quality Improvement Organizations (QIO), Reporting and record keeping requirements.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services is amending 42 CFR chapter IV as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

Subpart H—Payment to Hospitals Under the Prospective Payment Systems

■ 1. The authority citation for part 412 continues to read as follows:

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

■ 2. In § 412.115, revise paragraph (c) to read as follows:

§ 412.115 Additional payments.

* * * * *

(c) *QIO photocopy and mailing costs.* An additional payment is made to a hospital in accordance with § 476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

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

Subpart J—Prospective Payment 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), 1871, 1881, 1883, and 1886 of the Social Security Act (42 U.S.C. 1302, 1395d(d), 1395f(b), 1395l(a), (i), and (n), 1395hh, 1395rr, 1395tt, and 1395ww).

■ 2. Add a new § 413.355 to read as follows:

§ 413.355 Additional payment: QIO photocopy and mailing costs.

An additional payment is made to a skilled nursing facility in accordance with § 476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

PART 476—UTILIZATION AND QUALITY CONTROL REVIEW

Subpart C—Review Responsibilities of Quality Improvement Organizations (QIOs)

General Provisions

■ 1. The authority citation for part 476 continues to read as follows:

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

■ 2. In § 476.78, revise the introductory text to paragraph (b); revise paragraphs (b)(2), and the introductory text to paragraph (c); add new paragraph (c)(4); and revise paragraph (d) to read as follows:

§ 476.78 Responsibilities of health care providers.

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(b) *Cooperation with QIOs.* Health care providers that submit Medicare claims must cooperate in the assumption and conduct of QIO review. Providers must—

* * * * *

(2) Provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. The provider must photocopy and deliver to the QIO all required information within 30 days of a request. QIOs pay providers paid under the prospective payment system for the costs of photocopying records requested by the QIO in accordance with the payment rate determined under the methodology described in paragraph (c) of this section and for first class postage for mailing the records to the QIO. When the QIO does postadmission, preprocedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

* * * * *

(c) *Photocopying reimbursement methodology for prospective payment system providers.* Providers subject to the prospective payment system are paid for the photocopying costs that are directly attributable to the providers' responsibility to the QIOs to provide photocopies of requested provider records. The payment is in addition to payment already provided for these costs under other provisions of the Social Security Act and is based on a fixed amount per page as determined by CMS as follows:

* * * * *

(4) CMS will periodically review the photocopy reimbursement rate to ensure that it still accurately reflects provider costs. CMS will publish any changes to the rate in a **Federal Register** notice.

(d) *Appeals.* Reimbursement for the costs of photocopying and mailing records for QIO review is an additional payment to providers under the prospective payment system, as specified in § 412.115, § 413.355, and § 484.265 of this chapter. Thus, appeals concerning these costs are subject to the review process specified in part 405, subpart R of this chapter.

PART 484—HOME HEALTH SERVICES

Subpart E—Prospective Payment System for Home Health Agencies

■ 1. The authority citation for part 484 continues to read as follows:

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

■ 2. Add a new § 484.265 to read as follows:

§ 484.265 Additional payment.

QIO photocopy and mailing costs. An additional payment is made to a home health agency in accordance with § 476.78 of this chapter for the costs of photocopying and mailing medical records requested by a QIO.

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

Dated: May 23, 2003.

Thomas A. Scully,
Administrator, Center for Medicare & Medicaid Services.

Approved: August 28, 2003.

Tommy G. Thompson,
Secretary.

[FR Doc. 03–30096 Filed 11–28–03; 11:32 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 414

[CMS–1232–FC]

RIN 0938–AM44

Medicare Program; Coverage and Payment of Ambulance Services; Inflation Update for CY 2004

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

ACTION: Final rule with comment period.

SUMMARY: This final rule provides the sunset date for the interim bonus payment for rural ambulance mileage of 18 through 50 miles as required by the Medicare, Medicaid and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA) and provides notice of the annual Ambulance Inflation Factor (AIF) for ambulance services for calendar year (CY) 2004. The statute requires that this inflation factor be