

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 410

[CMS-1436-P]

RIN 0938-AR06

Medicare Program; Clinical Laboratory Fee Schedule: Signature on Requisition

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would retract the policy adopted in the calendar year 2011 Physician Fee Schedule final rule with comment period that requires the signature of a physician or qualified non-physician practitioner on a requisition for clinical diagnostic laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS). In addition, this proposed rule would reinstate the prior policy that the signature of a physician or qualified non-physician practitioner is not required on a requisition for Medicare purposes for a clinical diagnostic laboratory test paid under the CLFS.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. eastern daylight time (e.d.t.) on August 29, 2011.

ADDRESSES: In commenting, please refer to file code CMS-1436-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <http://www.regulations.gov>. Follow the instructions for "submitting a comment."

2. By regular mail. You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1436-P, P.O. Box 8013, Baltimore, MD 21244-8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1436-P, Mail

Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-8013

4. By hand or courier. Alternatively, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201

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

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-1066 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the close of the comment period.

FOR FURTHER INFORMATION CONTACT: Glenn McGuirk, (410) 786-5723.

SUPPLEMENTARY INFORMATION:

I. Background

A. History and Overview

In the March 10, 2000 **Federal Register** (65 FR 13082), we published a proposed rule entitled "Medicare Program; Negotiated Rulemaking: Coverage and Administrative Policies for Clinical Diagnostic Laboratory Services," to announce and solicit comments on the results of our negotiated rulemaking committee tasked to establish national coverage and administrative policies for clinical diagnostic laboratory services payable under Part B of Medicare.

In the November 23, 2001 **Federal Register** (66 FR 58788), we published a final rule, which established these national coverage and administrative policies. In that final rule, we explained our policy on ordering clinical diagnostic laboratory services and revised regulatory language in § 410.32. Our regulation at § 410.32(a) includes a

requirement that states "[a]ll diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who is treating the beneficiary." In the November 23, 2001 final rule (66 FR 58809), we added paragraph (d)(2) to § 410.32 to require that the physician or qualified nonphysician practitioner (NPP) (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse-midwives, nurse practitioners, and physician assistants) who orders the service must maintain documentation of medical necessity in the beneficiary's medical record. In both the March 10, 2000 proposed rule (65 FR 13089) and the November 23, 2001 final rule (66 FR 58802), we noted that "[w]hile the signature of a physician on a requisition is one way of documenting that the treating physician ordered the test, it is not the only permissible way of documenting that the test has been ordered." In the preamble of these rules, we described the policy of not requiring physician signatures on requisitions for clinical diagnostic laboratory tests, but implicitly left in place the existing requirements for a written order to be signed by the ordering physician or NPP for clinical diagnostic laboratory tests, as well as other types of diagnostic tests. We further stated, in the March 10, 2000 proposed rule (65 FR 13089) and the November 23, 2001 final rule (66 FR 58802), that we would publish instructions to Medicare contractors clarifying that the signature of the ordering physician or NPP on a requisition for a clinical diagnostic laboratory test, is not required for Medicare purposes.

On March 5, 2002, we issued a program memorandum (Transmittal AB-02-030, Change Request 1998) implementing the administrative policies set forth in the November 23, 2001 final rule, including the following instruction:

Medicare does not require the signature of the ordering physician on a laboratory service requisition. While the signature of a physician on a requisition is one way of documenting that the treating physician ordered the service, it is not the only permissible way of documenting that the service has been ordered. For example, the physician may document the ordering of specific services in the patient's medical record.

On January 24, 2003, we issued a program transmittal (Transmittal 1787, Change Request 2410) to manualize the March 5, 2002 program memorandum. The transmittal page stated, "Section 15021, Ordering Diagnostic Tests, manualizes Transmittal AB-02-030, dated March 5, 2002. In accordance

with negotiated rulemaking for outpatient clinical diagnostic laboratory services, no signature is required for the ordering of such services or for physician pathology services.” In the manual instructions in that transmittal (that is, Transmittal 1787), we stated in a note: “No signature is required on orders for clinical diagnostic tests paid on the basis of the physician fee schedule or for physician pathology services.” The manual instructions inadvertently omitted the reference to clinical diagnostic laboratory tests. Thus, the transmittal seemed to extend the policy set forth in the November 23, 2001 final rule (that no signature is required on requisitions for clinical diagnostic laboratory tests paid under the clinical laboratory fee schedule (CLFS)) to also apply to clinical diagnostic tests paid on the basis of the physician fee schedule (PFS) and physician pathology services. In addition, the manual instructions used the term “order” instead of “requisition,” which some members of the industry have asserted caused confusion. When we transitioned from paper manuals to the current electronic Internet Only Manual (IOM) system, these manual instructions were inadvertently omitted from the new Benefit Policy Manual (BPM).

On August 28, 2008, we issued a program transmittal (Transmittal 94, Change Request 6100) to update the BPM to incorporate language that was previously contained in section 15021 of the Medicare Carriers Manual. The reissued language stated, “No signature is required on orders for clinical diagnostic tests paid on the basis of the clinical laboratory fee schedule, the physician fee schedule, or for physician pathology services.” After the publication of the August 2008 Program Transmittal (Transmittal 94), we received numerous inquiries from laboratories, diagnostic testing facilities, and hospital representatives who had questions about whether the provision applied to all diagnostic services, including x-rays, magnetic resonance imaging (MRIs), and other nonclinical laboratory fee schedule diagnostic services.

To resolve any existing confusion surrounding the implementation of the CLFS policy in 2001 and subsequent transmittals, we restated and solicited public comments on our policy in the July 13, 2009 proposed rule (74 FR 33641 and 33642), entitled “Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2010” (hereinafter referred to as the CY 2010 PFS proposed rule). At that time, our

policy was that the signature of a physician or NPP was not required on a requisition for clinical diagnostic laboratory tests paid on the basis of the CLFS. However, we were clear that we would still require that it must be evident, in accordance with our regulations at § 410.31(d)(2) and (3), that the physician or NPP had ordered the services.

We clarified that this policy regarding requisitions for clinical diagnostic laboratory tests would not supersede other applicable Medicare requirements (such as those related to hospital conditions of participation (CoPs)), which require the medical record to include an order signed by the physician or NPP who is treating the beneficiary. In addition, we stated that we did not believe that our policy regarding signatures on requisitions for clinical diagnostic laboratory tests supersedes other requirements mandated by professional standards of practice or obligations regarding orders and medical records promulgated by Medicare, the Joint Commission, or State law; nor did we believe the policy would require providers to change their business practices.

In the CY 2010 PFS proposed rule (74 FR 33641 and 33642), we also restated and solicited public comment on our longstanding policy, consistent with the principle in § 410.32(a) that a written order for diagnostic tests including those paid under the CLFS and those that are not paid under the CLFS (for example, that are paid under the PFS or under the OPSS), such as X-rays, MRIs, and the technical component (TC) of physician pathology services, must be signed by the ordering physician or NPP. We were clear that the policy that signatures are not required on requisitions for clinical diagnostic laboratory tests paid based on the CLFS applied only to requisitions (as opposed to written orders).

Additionally, in the CY 2010 PFS proposed rule (74 FR 33642) we solicited public comments about the distinction between an order and a requisition. We noted that an “order” as defined in our Internet Only Manual (IOM), 100–02, Chapter 15, Section 80.6.1, is a communication from the treating physician or NPP requesting that a diagnostic test be performed for a beneficiary. The order may conditionally request an additional diagnostic test for a particular beneficiary if the result of the initial diagnostic test ordered yields a certain value determined by the treating physician or NPP (for example, if test X is negative, then perform test Y). We further clarified in the CY 2010 PFS

final rule with comment period (74 FR 61930) that an order may be delivered via any of the following forms of communication:

- A written document signed by the treating physician or NPP, which is hand-delivered, mailed, or faxed to the testing facility.
- A telephone call by the treating physician or NPP or his or her office to the testing facility.
- An electronic mail, or other electronic means, by the treating physician or NPP or his or her office to the testing facility.

If the order is communicated via telephone, both the treating physician or NPP, or his or her office, and the testing facility must document the telephone call in their respective copies of the beneficiary’s medical records.

In the CY 2010 PFS proposed rule (74 FR 33642), we defined a “requisition” as the actual paperwork, such as a form, which is furnished to a clinical diagnostic laboratory that identifies the test or tests to be performed for a patient. The requisition may contain patient information, ordering physician information, referring institution information, information on where to send reports, billing information, specimen information, shipping addresses for specimens or tissue samples, and checkboxes for test selection. We believed the requisition was ministerial in nature, assisting laboratories with the billing and handling of results, and serves as an administrative convenience to providers and patients. We believed that a written order, which may be part of the medical record, and the requisition, were two different documents, although a requisition that is signed may serve as an order.

During the public comment period for the CY 2010 PFS proposed rule, we received numerous comments on these issues. Subsequently, in the CY 2010 PFS final rule with comment period (74 FR 61931), we stated that we would continue to carefully consider the issue of physician signatures on requisitions and orders and that we planned to revisit these issues in the future.

In the CY 2011 PFS proposed rule (75 FR 40162 through 40163), we proposed to require a physician’s or NPP’s signature on requisitions for clinical diagnostic laboratory tests paid on the basis of the CLFS. We stated that we believed this policy would result in a less confusing process because a physician’s signature would be required for all requisitions and orders, eliminating the uncertainty over whether the documentation is a requisition or an order, whether the type

of test being ordered requires a signature, or which payment system does or does not require a physician's or NPP's signature. We also stated that we believed the requirement would not increase the burden on physicians and would be easier for the reference laboratory technicians to know whether a test is appropriately requested, which would minimize potential compliance problems for laboratories during the course of a subsequent Medicare audit because a signature would be consistently required. We solicited public comments on the CY 2011 PFS proposed rule.

After careful consideration of all the comments received, we finalized our proposed policy without modification to require a physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS in the CY 2011 PFS final rule with comment period (75 FR 73483), which became effective on January 1, 2011. This policy did not affect physicians or NPPs who chose not to use requisitions to request clinical diagnostic laboratory tests paid under the CLFS. Such physicians or NPPs could continue to request such tests by other means, such as by using the annotated medical records, documented telephonic requests, or electronic requests.

II. Provisions of the Proposed Rule

In this proposed rule, we would retract the policy we finalized in the CY 2011 PFS final rule with comment period (75 FR 73483) and reinstate the prior policy that the signature of the physician or NPP is not required on a requisition for Medicare purposes for a clinical diagnostic laboratory test paid under the CLFS. We are proposing this policy based on continued and new concerns noted by stakeholders regarding the practical effect of the finalized policy on beneficiaries, physicians, and NPPs.

While we did not solicit further comments on the signature on requisition issue in the CY 2011 PFS final rule with comment period, we did receive additional feedback from industry stakeholders on the issue after its publication in the **Federal Register**. Industry stakeholders identified many scenarios where it would be difficult to obtain the physician's or NPP's signature on the requisition for clinical diagnostic laboratory tests under the CLFS. Industry stakeholders asserted that there are many different situations where the physician or NPP would direct staff to prepare requisitions for laboratory tests, but then would be unavailable to provide his or her signature on the requisition. As an

example, and one that was raised by commenters to the CY 2011 PFS proposed rule, in the long-term care setting, the physician is typically not available in person on a daily basis. In these cases, the physician may keep abreast of the patient's condition by calling the nursing staff. If a patient's condition indicates that a clinical diagnostic laboratory test is required, the nursing staff typically transcribes the order from the physician over the telephone onto a requisition. The information has to be transmitted to the laboratory and, in this scenario, there is no physician's or NPP's signature on the requisition. Another example that occurs in many settings, including nursing homes, all types of hospitals (inpatient as well as outpatient), and physician offices, involves specimens that are packaged for transmission to the laboratory with a requisition by nursing staff. Because the specimen often is transferred directly from the patient to the nursing staff without, in most cases, a physician's or NPP's intervention, the requisition that accompanies the specimen does not bear the signature of the physician or NPP.

Even in cases where the physician or NPP sees the patient in his/her offices for an appointment and recommends that clinical diagnostic laboratory testing be performed, we now better understand that, typically, the information is transcribed from the medical record onto a paper requisition by office staff after the physician or NPP and the patient have concluded their interaction. In practice, we can see how requiring the physician or NPP to sign the paper requisition could, in some cases, be very inconvenient and disruptive to the physician, NPP, the beneficiary, and other patients. The physician or NPP may need to take time either during appointments with subsequent patients or between patient appointments to make sure that the requisition is signed for a particular patient prior to his/her departure from the office. In addition, a beneficiary might have to wait for a physician or NPP to complete the requisition signature process before the beneficiary could depart from the office.

Another situation identified by industry stakeholders that we did not previously consider concerns physicians or NPPs who maintain several practice locations. A patient may see his or her physician or NPP only at one particular practice location. If that patient presents to the practice location with a medical issue that the physician or NPP believes warrants immediate laboratory testing, but the physician or NPP is physically at a different location

that day, the physician or NPP may be able to direct his or her nursing staff to prepare a requisition for the laboratory test. But, if the physician or NPP must sign the requisition, there could be a delay of several days or longer, before the physician or NPP is able to do so, which means the patient would have to wait to have the laboratory test performed.

The aforementioned scenarios have detrimental implications for expeditious patient care that were not evident to us until the new policy was effectuated and we started hearing from stakeholders in the industry that would be negatively impacted by the policy. In response to a comment suggesting that physicians be educated about this new requirement to alleviate problems of non-compliance, we stated, in the CY 2011 PFS final rule with comment period (75 FR 73482), that we would update our manuals and direct the Medicare contractors to educate physicians and NPPs on this policy. After publication of the CY 2011 PFS final rule with comment period, it became even clearer to us that some physicians, NPPs, and clinical diagnostic laboratories were not aware of, or did not understand, the policy. Therefore, in the first calendar quarter of 2011, we focused on developing educational and outreach materials to educate those affected by this policy. Further, we issued a statement that, once the first quarter of 2011 educational campaign is fully underway, we would expect requisitions to be signed. While developing educational and outreach materials, we realized how difficult and burdensome the actual implementation of this policy was for physicians and NPPs and that, in some cases, the implementation of this policy could have a negative impact on patient care. At that point, we decided that the better course of action was to re-examine the policy.

We re-examined our policy and our reasons for adopting this policy in light of industry stakeholders' comments received after publication of the CY 2011 PFS final rule with comment period and comments received on the CY 2011 PFS proposed rule. We reviewed our beliefs and assumptions regarding the effect of our policy on access to care and with respect to administrative burden on physicians and NPPs, the effect on innovation, and the impact on laboratories. We believed that the policy would not have a negative impact on beneficiary access to care. However, we now believe that we underestimated the potential impact on beneficiary health and safety. As

discussed previously, care may be delayed under this policy in situations where the physician or NPP orders the test but is not available onsite to sign the requisition. For example, we understand there are concerns that certain populations of patients, such as nursing home patients and patients confined to their homes, may have laboratory tests ordered urgently by a distant physician or NPP to obtain information that is imminently needed in order to assess a need for immediate referral to a hospital, emergency department or other facility. If the ordering physician or NPP is not onsite, it is unlikely that he or she would be able to receive, sign, and return a requisition in the timeframe needed to respond to the patient's urgent clinical status. We had not anticipated this impact on care when we finalized our policy.

We also believed that the administrative burden on physicians and NPPs would be minimal and would result in a less confusing process. Physicians and NPPs must document their orders, in some form, in one or more of the medical records of the patient. We still believe that signing a laboratory requisition at the time of the order, if the requisition is ready for signature, imposes little burden on the physician or NPP, while significantly increasing our ability to minimize improper payments due to fraud and abuse. However, we believe we may have underestimated the number of occasions in which the physician or NPP cannot perform both steps concurrently. We now understand that it is not always the case that a physician or NPP can perform both steps concurrently. For instance, a physician may sign an order at the time of delivering care, but the requisition may not be available for signature until sometime later. In that situation, the physician may need to interrupt a subsequent examination in order to sign a completed requisition so that the patient may leave with the requisition. Given recently released estimates of physician shortfalls in primary care (as referenced in remarks by the Health Resources and Services Administration (HRSA) Administrator to the Bureau of Health Professions Advisory Committee on April 21, 2009), the cost of lost physician time must also be revalued upwards. Alternatively, the beneficiary may have to wait for the physician or NPP to conclude his/her subsequent appointment, which could be as long as 30 minutes or more. Neither of these situations—interrupting the physician or NPP in a subsequent appointment or

making the beneficiary wait for an inconvenient period of time—is acceptable. Further, we believed that the policy resulted in a less confusing process because a physician or NPP signature would be required for all requisitions and orders, eliminating uncertainty over whether the documentation is a requisition or an order, whether the type of test being ordered requires a signature, or which payment system does nor does not require a physician or NPP signature. However, based on industry stakeholder comments subsequent to the publication of the CY 2011 PFS final rule with comment period, we now believe this process may not be less confusing. Further, industry stakeholders assured us that they had not been confused about the former physician signature policy and that they never intended for us to interpret their call for consistency in the signature process to mean that they should be burdened with an additional requirement when they were already signing the medical record.

In addition, we believed that many stakeholders either had converted or were in the process of converting to an electronic health records process that would negate the need for a requisition. Electronic health records and electronic transmission of health information are key pieces of this Administration's economic recovery plan and, moreover, are key elements of our plan to improve healthcare quality and efficiency. From the additional stakeholder concerns subsequent to our CY 2011 PFS final rule with comment period, we are sensitive to the increasing migration of information transfer away from paper forms, such as requisitions, to the direct electronic submission of requests for services. After we adopted the new policy, stakeholders expressed their concerns that the requirement for a signature would increase paperwork, in direct opposition to our promotion of time-saving electronic communications. We believe that the requirement for a signature on the requisition does not impact stakeholders who utilize an electronic process for ordering clinical diagnostic laboratory tests because the policy only applies to requisitions, which are paper forms. Our intent was not to suggest that a requisition was necessary in those cases. However, we recognize that members of the provider and supplier community believe that this regulation could inhibit their use of innovative technology and investment in healthcare IT resources even after we explained the issue. Therefore, we underestimated the potential for paperwork burden.

Finally, we believed that the policy would make it easier for a reference laboratory to know whether a test is appropriately requested and to minimize potential compliance problems. Specifically, we believe that the policy improves a laboratory's ability to authenticate requisitions. While we still believe this is true, based on industry stakeholder concerns received after the CY 2011 PFS final rule with comment period, which elaborated on comments submitted in response to the CY 2011 PFS proposed rule (75 FR 40161 through 40163), we now believe our estimate of the financial benefit of this aspect of the policy is less than we originally believed, because the percentage of laboratory requests actually covered by this policy may be smaller than we originally predicted and may continue to shrink as new technology is adopted. We also believed the policy provided a mechanism for laboratories to fulfill their responsibility to ensure that they only provide and bill for services on the direct order of a physician or NPP as the signature on the requisition would provide documentation and evidence that the physician or NPP had ordered the service. However, industry stakeholders expanded on comments to the CY 2011 PFS proposed rule and informed us that there was a cost to adopting a rigid mechanism of establishing authenticity. Laboratories believe that it is more efficient for them to use internal procedures and controls to ensure that they do not provide and bill for services in the absence of a physician authorization rather than through a Federal policy. We believe that the benefits expected may be lower than we originally estimated.

In summary, there were many situations that we could not recognize as problematic until we finalized the new policy and stakeholders began to implement. Upon review of the concerns that industry stakeholders raised after we finalized our policy in the CY 2011 PFS final rule with comment period, and in reconsideration of comments to the CY 2011 PFS proposed rule, we propose to retract the policy that was finalized in the CY 2011 PFS final rule with comment period, which required a physician's or NPP's signature on a requisition for clinical diagnostic laboratory tests paid under the CLFS (75 FR 73483) and we propose to reinstate our prior policy that the signature of the physician or NPP is not required on a requisition for a clinical diagnostic laboratory test paid under the CLFS for Medicare purposes.

We remain concerned about the costs and impact of fraud and abuse on the

Medicare program. The requirement that the treating physician or NPP must document the ordering of the test remains, as does our longstanding policy that requires orders, including those for clinical diagnostic laboratory tests, to be signed by the ordering physician or NPP. We believe that all parties share in the responsibility of ensuring that Medicare services are provided only in accordance with all applicable statutes and regulations, such as the requirement for a physician or NPP order. In many instances, such as in the case of orders originating in hospitals, we believe that retaining all the other requirements previously discussed, especially requiring the physician or NPP who orders the service to maintain documentation of medical necessity in the beneficiary's medical record according to § 410.32(d)(2)(i), as well as the hospital CoPs on medical record services at § 482.24, are sufficient. However, we note that hospital CoPs do not apply to other settings, such as private offices.

We believe that it is the responsibility of the clinical diagnostic laboratory, as it is for the provider of any service, to have sufficient processes and safeguards in place to ensure that all services are delivered only when ordered by the physician or NPP. This proposed rule does not preclude an individual laboratory from requiring a physician's or NPP's signature on the requisition. The laboratory may develop its own compliance procedures to ensure that it only furnishes services in response to a physician or NPP order. Such procedures could include internal audits, agreements with ordering physicians or NPPs to provide medical record evidence of the order in the event of an internal or external audit, steps to confirm the existence of an order under certain circumstances, or any other measures including the acceptance of risk by the clinical laboratory. We believe that this financial and compliance responsibility was implicit in the 2001 final rule (66 FR 58788), was reiterated in the March 5, 2002 transmittal (Change Request 2410, Transmittal AB-02-030), and has remained a consistent element of the subsequent instructions.

III. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

IV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year) or that adversely affect, in a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal government or communities. There are no expenditures or fiscal impact on the Medicare program associated with the policy discussed in this proposed rule. While the policy that is proposed for reinstatement in this proposed rule may have an effect on beneficiaries, we believe that any effect would be positive as we are changing a requirement that might have impeded access to care in some cases. There are no proposed policies in this proposed rule that impact payment rates under the clinical laboratory fee schedule, or any other part of the Medicare program. Therefore, for the change in policy regarding the

physician's or NPP's signature on requisitions for clinical diagnostic laboratory tests paid under the CLFS, this proposed rule does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Many hospitals and many other providers and suppliers are small entities, either by nonprofit status or by meeting the Small Business Administration (SBA) definition of a small business. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the Secretary has determined that this proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act (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 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98-21) designated hospitals in certain New England counties as belonging to the adjacent urban areas. Thus, for our purposes, we continue to classify these hospitals as urban hospitals. We are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this proposed rule, if finalized, would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2011, that threshold is approximately \$136 million. This proposed rule, if finalized, would have no consequential effect on State, local, or tribal governments 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 requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this proposed regulation does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this proposed rule was not reviewed by the Office of Management and Budget.

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

Dated: June 2, 2011.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

Approved: June 24, 2011.

Kathleen Sebelius,
Secretary, Department of Health and Human Services.

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