DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482 and 485

[CMS–3244–P]

RIN 0938–AQ89

Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the requirements that hospitals and critical access hospitals (CAHs) must meet to participate in the Medicare and Medicaid programs. These proposed changes are an integral part of our efforts to reduce procedural burdens on providers. This proposed rule reflects the Centers for Medicare and Medicaid Services' (CMS') commitment to the general principles of the President's Executive Order 13563, released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.''

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 23, 2011.

ADDRESSES: In commenting, please refer to file code CMS–3244–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 ''Submit a comment'' instructions.

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–3244–P, P.O. Box 8010, Baltimore, MD 21244–8010. 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–3244–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

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

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, call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT:

CDR Scott Cooper, USPHS, (410) 786–9465.

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SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this proposed rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code (CMS–3244–P) and the specific ''issue identifier'' that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov.* Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

Acronyms

AHA American Hospital Association
AOA American Osteopathic Association
APRN Advanced Practice Registered Nurse
BBA Balanced Budget Act
CAH Critical Access Hospital
CCN CMS Certification Number
CDC Centers for Disease Control and Prevention
CfC Condition for Coverage
CoP Condition of Participation
CMS Centers for Medicare & Medicaid Services
DNV Det Norske Veritas
EACH Essential Access Community Hospital
H&P History and Physical Examination
HAI Healthcare-Associated Infection
HFAP Healthcare Facilities Accreditation Program
HHS U.S. Department of Health and Human Services
MRHFP Medicare Rural Hospital Flexibility Program
OBRA Omnibus Budget Reconciliation Act
OPO Organ Procurement Organization
PA Physician Assistant
RIA Regulatory Impact Analysis
RFA Regulatory Flexibility Act
RPCH Rural Primary Care Hospital
SBA Small Business Administration
SBREFA Small Business Regulatory Enforcement Fairness Act
UMRA Unfunded Mandates Reform Act

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This proposed rule is organized as follows:

I. Background

A. Introduction

This proposed rule reflects the Centers for Medicare and Medicaid Services' (CMS') commitment to the general principles of the President's Executive Order 13563, released January 18, 2011, entitled ''Improving Regulation and Regulatory Review.'' In this proposed rule we seek to reduce the regulatory burden placed on hospitals. We have identified a number of existing hospital CoPs that we believe could be reformed, simplified, or eliminated in order to reduce unnecessary burden and costs placed on hospitals and critical access hospitals (CAHs) under existing regulations. Earlier this year, the President reaffirmed his commitment to Executive Order 12866, which was issued in 1993 and has long governed the process of regulatory development and review. He also issued Executive Order 13563 directing agencies to select the least burdensome approaches, to minimize cumulative costs, to simplify and harmonize overlapping regulations, and to identify and consider flexible approaches that maintain freedom of choice for the American public. Executive Order 13563 also requires agencies to engage in a process of reviewing existing regulations to see if those rules make sense and continue to be justified. The reforms contemplated in this proposed rule are intended to meet the letter and spirit of the requirement in the President's Executive Order 13563, issued January 18, 2011, entitled ''Improving Regulation and Regulatory Review,'' for reviewing existing regulations to see if those rules make sense and continue to be justified. They also meet the objectives of section 610 of the Regulatory Flexibility Act (RFA), which also requires agencies to review the impact of existing rules on small businesses or other small entities for possible reforms to reduce burden and costs.

Under this initiative, we are conducting a retrospective review of the CoPs that we apply to hospitals, in order to remove or revise obsolete, unnecessary, or burdensome provisions. Most of the existing hospital requirements have developed over decades, reflecting new statutory requirements, changes in technology or medical practice, and the evolution of the health delivery system. The goal of this retrospective review is to reduce system costs by removing obsolete or burdensome requirements.

B. Legal Basis and Purpose of Hospital CoPs

Sections 1861(e)(1) through (8) of the Social Security Act (the Act) provide that a hospital participating in the Medicare program must meet certain specified requirements. Section 1861(e)(9) of the Act specifies that a hospital also must meet such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals furnished services in the institution. Under this authority, the Secretary has established regulatory requirements that a hospital must meet to participate in Medicare at 42 CFR part 482, CoPs for Hospitals. Section 1905(a) of the Act provides that Medicaid payments from States may be applied to hospital services. Under regulations at 42 CFR 440.10(a)(3)(iii) and 42 CFR 440.20(a)(3)(ii), hospitals are required to meet the Medicare CoPs in order to participate in Medicaid.

On May 26, 1993, CMS published a final rule in the **Federal Register** entitled ''Medicare Program; Essential Access Community Hospitals (EACHs) and Rural Primary Care Hospitals (RPCHs)'' (58 FR 30630) that implemented sections 6003(g) and 6116 of the Omnibus Budget Reconciliation Act (OBRA) of 1989 and section 4008(d) of OBRA 1990. That rule established requirements for the EACH and RPCH providers that participated in the seven-state demonstration program that was designed to improve access to hospital and other health services for rural residents.

Sections 1820 and 1861(mm) of the Act, as amended by section 4201 of the Balanced Budget Act (BBA) of 1997, replaced the EACH/RPCH program with the Medicare Rural Hospital Flexibility Program (MRHFP), under which a qualifying facility can be designated as a CAH. CAHs participating in the MRHFP must meet the conditions for designation specified in the statute and, under section 1820(c)(2)(B)(i)(I) of the Act, must meet the CoPs located at 42 CFR part 485, subpart F. Among such requirements, a CAH must be located in a rural area (or an area treated as rural) and must be located more than a 35-mile (or in the case of mountainous terrain or in areas with only secondary roads available, more than a 15-mile drive) from a hospital or another CAH unless otherwise designated as a necessary provider prior to January 1, 2006.

The CoPs are organized according to the types of services a hospital may offer, and include specific, process oriented requirements for each hospital service or department. The purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare-participating hospitals. In accordance with Section 1864 of the Act, State surveyors assess hospital compliance with the conditions as part of the process of determining whether a hospital qualifies for a provider agreement under Medicare. However, under section 1865 of the Act, hospitals can elect to be reviewed instead by private accreditation organizations approved by CMS as having standards and survey procedures that are at least equivalent to those used by CMS and State surveyors. CMS-approved hospital accreditation programs include those of The Joint Commission (TJC), the American Osteopathic Association/ Healthcare Facilities Accreditation Program (AOA/HFAP), and Det Norske Veritas Healthcare (DNV) (See 42 CFR part 488, Survey and Certification Procedures.).

C. Relationship of This Rulemaking to Future Reforms

The reforms we propose in this rule are intended to reduce the cost and burden of existing CoPs. They are based in large part on ideas that have been provided to us by hospitals and organizations representing hospitals, by health care professionals, and by other stakeholders, as well as through recent research and our own evaluation of current practices. We are committed to working with, and welcome suggestions for future rulemaking from, affected parties to identify other reforms to the CoPs that would reduce unnecessary burden on hospitals, while allowing hospitals maximum flexibility in meeting the Federal requirements necessary to fulfill our quality of care responsibilities.

II. Provisions of the Proposed Regulations

In accordance with the President's Executive Order 13563, we are reviewing regulations in an effort to reduce burden, maximize patient safety, and reflect current industry standards. We have identified several priority areas in the CoPs for both hospitals (42 CFR part 482) and CAHs (42 CFR part 485) to update and revise. Our identification and prioritization of these areas was a result of outreach to hospital

stakeholders, such as the American Hospital Association (AHA) and TJC; and internal discussions among various components at CMS. We believe that these proposed revisions may eliminate or significantly reduce those instances where the CoPs are duplicative, unnecessary, and/or burdensome.

A. Revisions To Allow Flexibility and Eliminate Burdensome CoPs

1. Governing Body (§ 482.12)

We propose to revise the ''Governing body'' requirements as follows: The Governing body CoP (§ 482.12) states that the hospital must have an effective governing body that is legally responsible for the conduct of the hospital as an institution. We have interpreted the governing body CoP as requiring that each hospital facility have a separate governing body (*http://www.cms.gov/manuals/downloads/som107ap_a_hospitals.pdf*).

Based on our experience with hospitals and the input provided by stakeholders through anecdotal evidence, we believe that hospitals in a multi-hospital system (defined here as those having more than one CMS Certification Number (CCN)) can be effectively governed by a single governing body. Thus, we propose to revise and clarify the governing body requirement to reflect current hospital organizational structure whereby multi-hospital systems have integrated their governing body functions to oversee care in a more efficient and effective manner. Specifically, we propose to revise § 482.12 to state that ''There must be an effective governing body that is legally responsible for the conduct of the hospital.''

We would retain the current provision that requires the persons legally responsible for the conduct of the hospital to carry out the functions specified in Part 482 of our regulations that pertain to the governing body if the hospital does not have an organized governing body.

2. Patient's Rights (§ 482.13)

On December 8, 2006, we published a final rule in the **Federal Register** entitled ''Medicare and Medicaid Programs; Hospital Conditions of Participation: Patients' Rights'' (71 FR 71378). In that final rule we revised the hospital standards for the use of restraint and seclusion, and set forth new standards for staff training and death reporting. In particular, section 482.13(g) of the final rule requires hospitals to report no later than the close of business on the next business day following knowledge of the patient's death: (1) Each death that occurs while the patient is in restraint or seclusion; (2) each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; and (3) each death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that the restraint or seclusion contributed directly or indirectly to the patient's death.

Included under these broad reporting requirements are those deaths in which no seclusion is used, and the only restraints used are soft, two-point wrist restraints. The patients typically needing soft two-point wrist restraints are individuals in critical care settings, such as intensive care units, where such restraints are medically necessary. For example, soft two-point wrist restraints can be used to prevent patients from removing medically necessary devices and equipment such as central lines, endotracheal tubes, and nasogastric tubes. CMS is not aware of any research—or even any anecdotal information—suggesting a cause-and-effect relationship between the use of soft, two-point wrist restraints and patient deaths.

CMS is therefore proposing to modify the reporting requirements for hospitals when the circumstances of a patient's death involve only the use of soft two-point wrist restraints and no use of seclusion. At § 482.13(g)(4) we propose that hospitals would be required to notify CMS of the deaths described at § 482.13(g)(2) (soft two-point wrist restraints and no use of seclusion) within seven days after the date of death through a log or other system. We propose that the record would include, at a minimum, the patient's name, date of birth, date of death, attending physician, primary diagnosis(es), and medical record number. We propose that hospitals make the log or other system accessible to CMS upon request at all times. We are unable to eliminate the reporting requirement for these deaths due to statutory provisions in the Children's Health Act that require such deaths to be reported.

For deaths involving all other types of restraints and all forms of seclusion, we would retain the current, more extensive reporting requirements, including notice to CMS by telephone, no later than the close of business on the next business day following knowledge of the patient's death.

We are proposing to introduce a measure of flexibility to these requirements and redesignate them at § 482.13(g)(1), by providing additional reporting options, as determined by CMS, which would include the use of facsimile, as well as an option for electronic reporting. In the event that electronic reporting technology develops more rapidly than the requirements for this section, we have proposed the term ''electronically'' rather than ''email'' to build in a small measure of flexibility.

3. Medical Staff (§ 482.22)

The CMS condition of participation on ''Medical Staff,'' at § 482.22, concerns the organization and accountability of the hospital medical staff. CMS first adopted the term ''medical staff'' in 1986 when it began using the term at § 482.22 in place of ''physicians,'' to allow hospitals maximum flexibility in the granting of privileges and the organization of their professional staff (51 FR 22010). These changes were introduced to reflect the trend of extending patient care responsibilities to practitioners other than doctors of medicine or osteopathy. CMS has more recently modernized its approach to medical staff requirements with respect to telemedicine services through the rule ''Medicare and Medicaid Programs: Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging,'' that became effective July 5, 2011 (76 FR 25563).

CMS is now proposing to further modernize hospitals' medical staffing policies. We believe these changes would provide hospitals the clarity and flexibility they need under federal law to maximize their staffing opportunities for all practitioners, and particularly for non-physician practitioners, under their individual States' laws.

First, we propose to redesignate § 482.22(a)(2) to § 482.22(a)(5) and revise it by adding language to clarify that a hospital may grant privileges to both physicians and non-physicians to practice within their State scope of practice, regardless of whether they are also appointed to the hospital's medical staff. That is, technical membership in a hospital's medical staff would not be a prerequisite for a hospital's governing body to grant practice privileges to practitioners.

Hospitals wishing to bring on additional practitioners without also making them members of the medical staff would follow the same requirements specified in current regulation. That is, the medical staff would examine the credentials of each candidate and make recommendations to the governing body. Medical staff conducting the evaluations would operate under their own hospitals'

policies and procedures. Moreover, the medical staff would continue to be limited by State law, and thus would not be permitted to grant a practitioner candidate any privileges beyond those allowed in the State where the hospital is located, where he or she would ultimately practice.

We believe this proposed language would provide hospitals with the clarity they need to explore new and expanded approaches to care giving. Hospitals would be able to increase the number of practitioners who could perform various functions and duties, up to the regulatory boundaries allowed under their State licensing and scope of practice laws.

These proposed revisions are in response to requests received from stakeholders prior to the beginning of this rulemaking process. Many of these stakeholders expressed the opinion that some CMS requirements, particularly those related to medical staff, may stand in direct conflict with functions permitted under State practice acts and laws. In such cases, our requirements would be unnecessarily restricting the scope of practice of certain categories of non-physician practitioners (for example, Advanced Practice Registered Nurses (APRNs), Physician Assistants (PAs), Physical Therapists (PTs), Speech-language Pathologists (SLPs), and Doctors of Pharmacy (PharmDs)). Thus, stakeholders maintain, current regulatory impediments may be unduly limiting access to care and/or delaying treatment for patients and causing undue burden to practitioners (for example, the need to seek out physicians to co-sign orders). Our proposed changes would remove these barriers and allow hospitals to move forward in new ways to improve patient care, subject to State law.

The second area we propose to address relates to the general management and oversight of practitioners. Prior to the beginning of this rulemaking process, we received questions from some hospitals about the appropriate credentialing and privileging process for APRNs. We believe the changes we are proposing at § 482.22(a)(5) would address them. For example, some hospitals have questioned whether APRNs should be managed by the human resources department, as most registered nurses are, or by the medical staff, as most PAs are. We believe that, to the extent allowed under their States' law, most hospitals already manage and oversee the services of APRNs through their medical staffs. In fact, technically, our current regulations already allow hospitals to appoint non-physician practitioners as members of their medical staffs, if the State law in which their hospital operates permits it. However, the numerous questions we have received in this area indicate that our current regulation is unclear. Therefore, we are proposing language to revise the section by clarifying that being a member of a hospital's medical staff is not a prerequisite to being granted privileges in the hospital, regardless of whether a practitioner is a physician or a non-physician.

One of our chief concerns, in the context of proposing this change, is to ensure that all practitioners working at a hospital would continue to follow the rules set forth for ''Medical Staff'' at § 482.22. Thus, we are proposing language within this provision that would require those physicians and non-physicians, who have been granted practice privileges within their scope of practice but without appointment to the medical staff, to be subject to the requirements contained within this section. That is, they would be subject to the same hospital requirements, medical staff bylaws, and medical staff oversight as outlined under this CoP and to which appointed medical staff members are also subject. Alternatively, a hospital could establish categories within its medical staff to create distinctions between practitioners who have full membership and a new category for those who could be classified as having an ''associate,'' ''special,'' or ''limited'' membership. Such a structure is neither required nor suggested; we are providing it here as an example of one possible way for a hospital to align all of its practitioners under the ''Medical Staff'' rules.

We believe these proposed changes would complement and build upon present state and federal reform initiatives, including those set forth in the Affordable Care Act (ACA), to address the healthcare workforce shortages. We especially believe these proposed changes would support efforts to provide better health care in medically underserved communities. These changes would provide more flexibility to small hospitals and to critical access hospitals (CAHs) in rural areas and regions with a limited supply of primary care and specialized providers. They would also provide needed flexibility to hospitals located in impoverished urban centers. These changes would also provide States with additional regulatory flexibility to support their efforts to address the shortage of primary care providers.

The third area in which we are proposing changes concerns the more direct responsibilities for the organization and accountability of the medical staff. These requirements are set forth at § 482.22(b)(3). Presently, the hospital may assign these management tasks to either an individual doctor of medicine or osteopathy or, when permitted by State law of the State in which the hospital is located, a doctor of dental surgery or dental medicine. CMS proposes to expand the list to include doctors of podiatric medicine (DPMs). We believe this change would permit a podiatric physician to serve as the president, or its equivalent, of a hospital's medical staff in a significant number of states. CMS is aware that in such states, the laws underscore the widely held conclusion that the education, training, and experience of podiatric physicians are similar to that of their allopathic and osteopathic colleagues with respect to serving in such a hospital leadership position. With this proposed change, CMS wishes to ensure its hospital leadership requirements are not in conflict with State laws that would otherwise allow podiatric physicians to serve in this capacity. Moreover, CMS recognizes that the act of being selected as the president of the medical staff reflects the high level of confidence in which a candidate is held by his or her peers.

4. Nursing Services (§ 482.23)

We propose to revise the hospital nursing service requirements at § 482.23 (b)(4), ''Nursing services,'' which currently requires a hospital to ensure that the nursing staff develop, and keep current, a nursing care plan for each patient. We propose that for those hospitals that use an interdisciplinary plan of care in providing patient care, the care plan for nursing services be developed and kept current as part of the hospital's overall interdisciplinary care plan.

An interdisciplinary care plan optimizes the involvement of the various healthcare disciplines (such as nursing, respiratory care, occupational therapy, and pharmacy) to identify and document patient treatment goals and objectives, interventions, and progress in meeting those goals and objectives. We propose to revise our requirements to be less burdensome and more in line with current practice by proposing that, for those hospitals that use an interdisciplinary care plan, the nursing services care plan could be integrated into the overall hospital interdisciplinary care plan. This would decrease the burden of the nursing staff having to develop two care plans, one to fulfill the nursing services requirement and the other to fulfill the particular hospital's requirement for an

interdisciplinary care plan, and would improve the quality of patient care by the effective and timely communication of information pertaining to the nursing care of the patient.

We propose to revise the current Nursing services CoP at § 482.23(c) by adding new provisions that would allow for drugs and biologicals to be prepared and administered on the orders of practitioners other than those specified under § 482.12(c). We are also proposing a further revision to § 482.23(c) that would add a new provision allowing orders for drugs and biologicals to be documented and signed by practitioners other than those specified under § 482.12(c). We would allow for these two revisions only if such practitioners are acting in accordance with State law, including scope of practice laws, and only if the hospital has granted them privileges to do so.

These proposed revisions are in response to requests that CMS received from stakeholders prior to our beginning the rulemaking process. Many of these stakeholders expressed the opinion that some of the CMS requirements impede the scope of practice of certain categories of practitioners (for example, APRNs, PAs, and Doctors of Pharmacy (PharmDs)). They maintain that such regulatory impediments may limit access to care or delay treatment for patients; may cause undue burden to practitioners (for example, the need to seek out physicians to co-sign orders); and may stand in direct conflict with functions allowed under State practice laws.

In proposing these changes, we are aware that some States may not allow specific practitioners to exercise such privileges. We are also aware that some States may limit the categories of practitioners from which a registered nurse (as part of his or her scope of practice) may receive and carry out orders. However, we believe that these proposed revisions would not only allow hospitals to more fully use these practitioners in the care of patients, but that changes to what we view as unnecessary regulatory prohibitions would serve to greatly reduce the regulatory burden for hospitals and allow for more efficient care practices.

Within this section of the Nursing services CoP, we are also proposing changes that would allow hospitals to use standing orders. At § 482.23(c)(1)(ii), we propose to allow for the preparation and administration of drugs and biologicals on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders, but only if such orders meet the requirements of § 482.24(c)(3), as discussed below.

Much of the evidence on the effectiveness of hospital standing orders is in the context of their use by Rapid Response Teams (RRTs) and then only when applied in a very limited and focused manner. A search of the medical literature revealed that there may be additional areas where standing orders have some efficacy in the hospital setting. (*http://www.innovations.ahrq.gov/content.aspx?id=1750; http://www.cdc.gov/mmwr/PDF/rr/rr5416.pdf*).

These areas include:

- Emergency department (ED) admission/triage in particular for certain conditions such as acute asthma, acute myocardial infarction, and stroke (we would expect that standing orders would be authenticated by an ED physician or nonphysician practitioner when subsequent orders during the ED visit are authenticated for the patient);
- Improving immunization rates (beyond those for influenza and pneumococcal as currently allowed under the CoPs); and
- Postoperative recovery areas.

Although the current hospital CoPs already allow for nurse-initiated influenza and pneumococcal vaccinations (under medical staff-approved hospital policy), an expanded use of standing orders for other immunizations, which have clearly established and nationally recognized guidelines (for example, CDC guidelines for Hepatitis B vaccination of at-risk newborns), may be a mechanism, under the CoPs, for improved patient care.

We propose to eliminate the requirement, currently at § 482.23(c)(3), that non-physicians must have special training in administering blood transfusions and intravenous medications. We believe that this training is standard practice, and thus does not need to be prescribed in these regulations.

At § 482.23(c)(4) we propose that those who administer blood transfusions and intravenous medications do so in accordance with State law and approved medical staff policies and procedures. We propose to retain § 482.23(c)(4) and redesignate it at § 482.23(c)(5), without any content change.

We also propose additional revisions at proposed § 482.23(c)(6) that would allow hospitals the flexibility to develop and implement policies and procedures for a patient and his or her caregivers/support persons to administer specific medications (non-controlled drugs and biologicals).This proposal would be consistent with the current practice of giving patients access at the bedside to urgently needed medications, such as nitroglycerine tablets and inhalers, and selected non-prescription medications, such as lotions and rewetting eye drops. These proposed changes would apply to the self-administration of both hospital-issued medications and the patient's own medications brought into the hospital.

Hospitals that choose to develop and implement a program that allows for patients and caregivers/support persons to administer certain medications would be expected to address the program in their hospital policies and procedures. We would expect a collaborative effort by the hospital's medical staff, nursing department, and pharmacy department to develop these policies and procedures. A hospital would need to: assure that a practitioner had issued an order, consistent with hospital policy, permitting self-administration of medications; assess patient and caregiver/support person capacity to self-administer specific medications; provide patient and caregiver/support person instruction regarding the safe and accurate administration of the specified drugs and biologicals (for specific hospital-issued medications and, if determined to be needed, for a patient's own medications brought in from home); ensure the security of medications for each patient; identify a patient's own medications and visually evaluate those medications for integrity; and document the administration of each medication in the patient's medical record.

We believe that this provision, allowing for patient self-administration of medication, particularly those medications brought in from the patient's home, may provide hospitals with a means to make care more patient-centered and adaptable to patient and caregiver/support person needs.

Medical Record Services (§ 482.24)

On November 27, 2006, CMS published a final rule that made revisions to specific provisions of the hospital CoPs at 42 CFR part 482 (71 FR 68694). The current requirements, as finalized at § 482.24(c)(1)(i) in the 2006 rule, specify that all orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner. Also included in the rule was an exception to this requirement at § 482.24(c)(1)(ii), which allows, for the 5 year period following January 26, 2007, all orders, including verbal orders, to be dated, timed, and authenticated by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under

§ 482.12(c) and who is authorized to write orders by hospital policy in accordance with State law. When the rule was published in late 2006, the 5-year sunset provision was included with the thought that such an exception would not be needed five years hence since various technologies (for example, computerized physician order entry and authentication from a distance through a telecommunication medium) would have evolved and proliferated to the extent where in-person authentication by a practitioner would no longer be common or necessary. Though technologies have certainly advanced in the five years since publication of the rule, there is still not universal application and use of these advancements in hospitals or among practitioners.

Additionally, § 482.24(c)(1)(iii) establishes that all verbal orders must be authenticated based upon Federal and State law; in the absence of a State law designating a specific timeframe for the authentication of verbal orders, this provision then specifies that all verbal orders must be authenticated within 48 hours. Many stakeholders in the hospital community, including The Joint Commission and the American Hospital Association, have pointed out to us that this requirement is not only a particularly burdensome one for hospitals, but also one that does not have any appreciable benefit for patients with regard to safe care. We are proposing to consolidate three existing provisions into one new provision at § 482.24(c)(2). Specifically, we would remove existing paragraphs (c)(1)(i) through (c)(1)(iii) and add a new § 482.24(c)(2). Existing paragraph (c)(2) would be redesignated as (c)(3). This new provision would retain the requirement that all orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner, but would add the exception currently contained at § 482.24(c)(1)(ii) by allowing for authentication by either the ordering practitioner or ''another practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.'' In this way we would remove the sunset provision and the 48-hour timeframe requirement for authentication of orders and instead defer to hospital policy and State law for establishment of any timeframe. If there was no State law establishing such a timeframe, then a hospital would be allowed to establish their own timeframe for authentication of orders, including verbal orders.

Due to the risk of error involved in the use of verbal orders, we encourage hospitals to keep the use of such orders to a minimum and to establish policies that discourage their use. When verbal orders must be used, hospitals should have their own policies in place (*e.g.,* ''read-back and verify'' requirements) to ensure accuracy in the transcribing of orders, particularly those involving medication dosages.

As discussed above in the Nursing services CoP section, we are proposing changes to that CoP as well as to the Medical records services CoP that would allow hospitals to use standing orders as long as certain provisions were met. In this rule, we propose new provisions to § 482.24(c)(3) that would allow a hospital to use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital: (1) Establishes that such orders and protocols have been reviewed and approved by the medical staff in consultation with the hospital's nursing and pharmacy leadership; (2) demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines; (3) ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff, in consultation with the hospital's nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols; and (4) ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.

For additional guidance on the use of standing orders, stakeholders should review the CMS memorandum (CMS S&C–09–10) issued on October 24, 2008 (*http://www.cms.gov/SurveyCertificationGenInfo/downloads/SCLetter09-10.pdf*), where we pointed out our strong support of the use of evidence-based protocols, developed by the medical staff and based on recognized standards of practice, that advance the quality of care provided to patients. CMS, through the CoPs, requires hospitals and practitioners to take a thoughtful and responsible approach when using pre-printed and electronic standing orders, order sets, and protocols, particularly those orders that may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practicable for a nurse to obtain the order and authentication from the physician or practitioner prior to the provision of care. In all cases protocols and standing orders must be medically necessary for the patients to whom they are applied, and the treating physician must be able to modify, cancel, void or decline to authenticate orders that were not medically necessary in a particular situation. Under no circumstances should a hospital use standing orders in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders. Hospital policies and procedures that discuss the use of standing orders should address well-defined clinical scenarios as a standard of practice for the use of such orders. We would expect the policies and procedures to also address the process by which a standing order is developed; approved; monitored; initiated by authorized staff; and subsequently authenticated by physicians or practitioners responsible for the care of the patient. Under the CoPs, all orders, whether written or verbal, must be authenticated and documented in the patient's medical record by a practitioner responsible for the care of the patient.

We would also expect to see specific criteria for a nurse or other authorized personnel to initiate the execution of a particular standing order clearly identified in the protocol for the order, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified. Policies and procedures should also address the instructions that the medical, nursing, and other applicable professional staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders. An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter. Likewise, standing order policies and procedures must specify the process whereby the physician or other practitioner responsible for the care of the patient acknowledges and authenticates the initiation of all standing orders after the fact, with the exception of influenza and pneumococcal polysaccharide vaccines, which do not require such authentication in accordance with § 482.23(c)(2).

The policies and procedures must also establish a process for monitoring and evaluating the use of standing orders, including proper adherence to the order's protocol. There must also be a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions to pre-printed and electronic standing orders, order sets, and protocols.

We believe that these proposed changes would do much to advance the practice of evidence-based medicine and would ensure more consistent care for all patients.

6. Infection Control (§ 482.42)

CMS introduced Infection Control as a CoP in 1986 amidst growing recognition that infections and communicable diseases were potentially exposing hospital patients to significant pain and risk, and driving up direct hospital charges (51 FR 22010, 22027). The regulation increased hospital accountability and sought to identify, prevent, control, investigate, and report infections and communicable diseases of patients and hospital personnel. The regulation also established a requirement for hospitals to keep a log to identify problems and for improvement to be made when problems were identified.

Since this requirement was published, advances in infection control surveillance systems have made the need for a separate infection log obsolete. We have also received complaints from stakeholders that the log requirement is too prescriptive and burdensome. We therefore propose to eliminate the current requirement at § 482.42(a)(2), proposing instead to allow hospitals flexibility in their approach to the tracking and surveillance of infections. The modern surveillance systems already in use include infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions. These activities are already required at § 482.42(a)(1), which we propose to retain under § 482.42(a). Specifically, the infection control officer or officers are required to develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel. The requirements at § 482.42(a), together with modern surveillance practices, have made the requirement for a separate infection control log unnecessarily redundant and burdensome.

7. Outpatient Services (§ 482.54)

Under the CoPs, the provision of outpatient services is an optional hospital service. However, if a hospital provides outpatient services, the services must meet the needs of patients according to acceptable standards of practice as required at § 482.54. The current provision at § 482.54(b)(1) also requires the hospital to assign an individual to be responsible for outpatient services.

We are aware that increasingly more hospital services are offered as outpatient services today than when this particular CoP was first developed. As hospitals have expanded the outpatient services offered to patients, many hospitals have determined that it is in the best interests of patient safety and management practices to appoint more than one individual to oversee the various services offered and also to fully integrate their outpatient services with inpatient services. Additionally, these hospitals have realized that as they have expanded the variety of outpatient services offered, a single outpatient services leader may not possess the training and expertise to oversee the myriad services that the hospital is capable of providing in the outpatient setting. For example, a hospital that offers pediatric, gynecological, and orthopedic outpatient services may find it advantageous and more efficient to have each of these outpatient departments managed by a professional with a background and expertise in the relevant specialty and who is also responsible for these hospital departments in the inpatient setting. Rather than have just one individual, who may only have qualifications and experience in one of these areas, as the person responsible for only the outpatient services of all three specialties, hospitals would be able to make more efficient use of department directors who would oversee both inpatient and outpatient services for a particular specialty. In fact, the current regulations at § 482.54(a) require outpatient services to be, ''integrated with inpatient services.''

Under the current requirement at § 482.54(b)(1), hospitals that are using multiple leaders must hire another director to oversee these highly qualified and expert directors who are already exercising responsibility for their respective areas, often for both inpatient and outpatient services. We have reason to believe, and feedback from stakeholders has confirmed that this situation may be causing unnecessary staff costs, increased administrative burden, and confused chains of command within a hospital regarding its management of patient services.

Therefore, in this proposed rule, we are proposing revisions to this CoP that would allow hospitals greater flexibility in determining the management structure of outpatient services that would be tailored to the scope and complexity of the services offered by an individual hospital. We propose to change the existing provision at § 482.54(b) by revising the provision at § 482.54(b)(1) to allow hospitals to assign one or more individuals to be responsible for outpatient services. We also propose to revise the current provision at § 482.54(b)(2), which currently requires a hospital to have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, by proposing to add a measure of flexibility such that hospitals would make their personnel decisions based on the scope and complexity of outpatient services offered.

8. Transplant Center Process Requirements—Organ Recovery and Receipt (§ 482.92)

On March 30, 2007, CMS published a final rule entitled ''Medicare Program: Hospital Conditions of Participation: Requirements for Approval and Re-Approval of Transplant Centers To Perform Organ Transplants'' (72 FR 15198). This final rule set forth hospital CoPs for the approval and re-approval of transplant centers at 42 CFR part 482, subpart E, including § 482.92, the section involving blood type and other vital data verification. Likewise, CMS addressed the regulatory requirements for organ procurement organizations in the 2006 final rule entitled ''Medicare and Medicaid Programs; Conditions for Coverage for Organ Procurement Organizations (OPOs),'' which published in the May 31, 2006 **Federal Register** (71 FR 30982). This rule set forth the Conditions for Coverage (CfCs) for OPOs, and it, too, included requirements for blood type verification. The transplant center and OPO rules were designed to work in tandem to achieve CMS' goals of safe, effective, and efficient care for all patients. However, since the time of publication, CMS has become aware of the potential for duplicative, overlapping efforts related to blood type verification. This proposed rule would address this unnecessary duplication by removing certain blood type verification requirements for transplant centers set forth at § 482.92(a).

As further described below, the requirements set forth in the transplant center rule at § 482.92(a) and in the OPO rule at § 486.344(d)(2)(ii) and § 486.344(e) are redundant and burdensome for providers as presently structured. Each blood type and other data verification requires documentation which must be physically signed and retained. For cases where the recovery is conducted by a surgeon on call for the OPO recovering for his/her own program, both the OPO and transplant center rules apply. As a practical matter, this has meant one set of paperwork for each entity, and, in some cases, a third set of paperwork maintained with the surgeon's records. The transplant hospital must maintain a copy of its signed verification and make it available for the onsite surveyors of its organ transplant program. OPOs maintain blood matching documentation for their onsite surveyors as well. In practice, for such cases, this means organ recovery teams must produce and protect two sets of paperwork alongside the recovered organs.

In addition, because the ultimate recipient is not always known at the time of organ recovery, as there may be several potential matches pending the final receipt of lab work confirming the compatibility of various blood antigens, the management of paperwork verifying the blood types for each intended organ recipient becomes even more burdensome.

In order to reduce the amount of verification paperwork, CMS proposes to amend the existing regulations governing transplant centers by removing the provision at § 482.92(a) which requires the transplant team to verify blood type before organ recovery. We would redesignate current paragraph (b) and (c) as (a) and (b), respectively.

CMS is proposing this change in an effort to reduce administrative burden for transplant centers and the surgeons recovering for these centers. We believe this change will also remove any legal ambiguities which may arise on behalf of ''on-call'' organ recovery surgeons and team members who fall under both the rules of the OPOs they are removing the organs for and the rules of the transplant hospitals where they are privileged. The change also would produce cost savings because the ''extra'' verifications will no longer be conducted.

Because the blood type verification is conducted at numerous points in time and by multiple physicians and clinicians, CMS does not expect that this proposed change would impact transplant recipients in an adverse manner. In fact, we believe the changes are wholly in keeping with our overarching aims to (1) ensure timely care for patients who are waiting for organs for transplantation; and (2) establish sufficient quality and procedural standards to ensure that transplants are performed in a safe and efficient manner. CMS believes the overall impact of this change would be to free up time and resources for transplant recovery teams and centers. This change is thus expected to benefit all parties involved in the practice of organ transplantation.

Definitions (§ 485.602) and Provision of Services (§ 485.635)

The current CoP at § 485.602 and § 485.635(b) require CAHs to furnish certain types of services directly rather than through contracts or under arrangements. Specifically, the CoP at § 485.635(b) requires CAH staff to provide, as direct services, (1) diagnostic and therapeutic services that are commonly furnished in a physician's office or at another entry point into the health care system; (2) laboratory services; (3) radiology services; and (4) emergency procedures.

In our view, the current regulation does not provide sufficient flexibility for the CAH to address efficiencies and alleviate work force shortages by affiliating with other providers and entities, as well as by utilizing temporary agencies. Healthcare facilities in rural settings often face challenges due to limited resources, small size, and location with regard to recruiting and retaining appropriately qualified health care professionals as employees. Their inability to use contracted services in some situations in lieu of hiring employees to provide certain services, places an increased burden on CAHs. In particular, it may be more efficient for a CAH to contract with a provider in the quantity that the CAH requires, to effectively address the needs of its patients. Under the current CoP, however, the CAH cannot pursue this option for the required services in these specialty areas.

We believe that what is most important in terms of quality and safety of care is that these required services are made available by the CAH, not that the qualified professionals providing those services be employees of the CAH. The proposed revisions to § 485.635(b) would eliminate the requirement that CAH staff must provide certain services directly and changes the heading of the standard, ''Direct services,'' to ''Patient services.'' We also propose to revise the language in paragraphs § 485.635(b)(1) through (b)(4), ''that the CAH staff furnishes as direct services.'' We believe the proposed revisions will provide CAHs with additional flexibility, increase the ability of CAHs to provide services that are required to ensure access to care, decrease burden on CAHs, and positively impact the costs of health care delivery. We also propose to eliminate the definition of ''Direct Services'' at § 485.602 since it will no longer be applicable.

The governing body, or the person principally responsible for the operation of the CAH under § 485.627(b)(2), would continue to be responsible for all services furnished by the CAH whether or not they are furnished directly, under arrangements, or under agreements. The governing body or responsible person must ensure that all furnished services enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.

We believe that changing this requirement will alleviate an unnecessary burden on CAHs and provide greater access to quality health care.

B. Clarifying Changes

10. Pharmaceutical Services (§ 482.25) and Infection Control (§ 482.42)

We propose to make a minor technical change to the requirement at § 482.25(b)(6). The current requirement states that drug administration errors, adverse drug reactions, and incompatibilities must be reported to the hospital's quality assurance program, if appropriate. Additionally, we propose to make a minor technical change to the requirement at § 482.42(b)(1). The current requirement states that the chief executive officer, the medical staff, and the director of nursing services must ensure that the hospital-wide quality assurance program and training programs address problems identified by the infection control officer or officers. Therefore, in both § 482.25(b)(6) and § 482.42(b)(1) we propose to replace the term ''quality assurance program'' with the more current term ''quality assessment and performance improvement program.'' This change would clarify that we expect drug errors, adverse reactions, and incompatibilities to be addressed in a hospital's QAPI program, as required at § 482.21.

11. Personnel Qualifications (§ 485.604)

Many of the former EACH/RPCH CoPs were adopted for the new CAH program (see 62 FR 46008, August 29, 1997), including the definition for clinical

nurse specialist. In this NPRM we are proposing to revise the definition of a *clinical nurse specialist* at § 485.604(a) to reflect the definition in the statute at § 1861(aa)(5)(B). Specifically, we propose to change the definition at § 485.604(a) to state that a clinical nurse specialist is a registered nurse licensed to practice nursing in the State in which the clinical nurse specialist services are performed, that holds an advanced degree in a defined clinical area of nursing from an accredited educational institution.

12. Surgical Services (§ 485.639)

The current surgical services CoP was promulgated in 1995 (60 FR 45814, September, 1, 1995) to ensure adequate health and safety protection for patients. However, the provision of surgical services is not a required CAH service under the Act at section 1820(c); therefore, we are proposing to make changes to this CoP to clarify that it is an optional service for CAHs. The proposed technical change to the CoP introductory text is as follows:

''If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH or responsible individual in accordance with the designation requirements under paragraph (a) of this section.''

C. Other Options Considered

In addition to the proposals discussed above, we considered the alternative options, described below, for revising the CoPs.

Medical Staff (§ 482.22)

Similar to the changes proposed in this rule that would allow a multi-hospital system the option of having a single governing body legally responsible for the conduct of the hospital (§ 482.12), we considered changes to the Medical staff CoP at § 482.22 that would allow a multi-hospital system the option of having a single organized medical staff responsible for the quality of medical care provided to patients by all of the hospitals in the system. Stakeholders have reported that multi-hospital systems have both integrated their governing body functions and their medical staff functions to oversee patient care in a more efficient manner.

The current language of § 482.22 states that the hospital ''must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.'' We do not believe that the current Medical staff CoP language implies that we require a single and separate medical staff for each hospital within a multi-hospital system. Therefore, we have retained the current requirement without revision. However, based on the anecdotal evidence and input provided by stakeholders on this issue, we request comment on whether we need to propose any clarifying language.

Based on stakeholder feedback, we considered revising the overall organizational structure of the CoPs to condense current requirements for departmental leadership responsibilities into a single, non-specific CoP that would allow hospitals to appoint hospital leaders based on hospital-established qualifications and needs specific to each hospital. However, we believe that the department-specific organization of the current CoPs, and the current specialty-department-specific leadership requirements, are appropriate, and can be compatible with the leadership standards of our stakeholders. We are specifically seeking comment on this issue.

Medical Record Services (§ 482.24)

We considered modifying the regulatory requirement at current § 482.24(c)(2) to clarify the intent of the rule in situations where a patient has received a medical history and physical examination (H&P) by either a non-hospital practitioner or a practitioner with hospital privileges prior to the patient's hospital visit. When an H&P has been completed for a patient within the most recent 30-day period prior to the patient's admission or registration, the current regulation requires a hospital to ensure documentation of, ''[a]n updated examination of the patient, including any changes in the patient's condition. * * *''

We believe that some stakeholders may be interpreting our current requirements in a way that would require a hospital to conduct a full update to an H&P that was conducted within 30 days prior to the patient's admission or registration. As put forth in our November 27, 2006 final rule related to this issue (''Medicare and Medicaid Programs; Hospital Conditions of Participation: Requirements for History and Physical Examinations; Authentication of Verbal Orders; Securing Medications; and Postanesthesia Evaluations,'' 71 FR 68673, 68675) and as stated in our current Interpretive Guidelines (CMS. ''State Operations Manual.'' Pub 100–07, Appendix A, *http://cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf*), a hospital may adopt a policy allowing submission of an H&P prior to the patient's hospital admission or registration by a practitioner who may not be a member of the hospital's medical staff or who does not have admitting privileges by that hospital, or by a qualified licensed individual who does not practice at that hospital but is acting within his/her scope of practice under State law or regulation. When an H&P is completed within the 30 days before admission or registration, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is placed in the patient's medical record. This examination must be conducted by a practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P.

The update note to the H&P must document an examination for any changes in the patient's condition since the time that the patient's H&P was performed that might be significant for the planned course of treatment. If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that ''no change'' has occurred in the patient's condition since the H&P was completed. We note that we do not specify the extent of the examination that must be conducted; rather, we defer to the clinical judgment of hospital staff to determine the extent of the necessary H&P update. We believe that our interpretation of the H&P update requirement assures that all patients undergoing surgery or anesthesia are properly evaluated for all contraindications in accordance with the clinical judgment of hospital staff without an undue duplication of services and documentation. Therefore, we do not believe that the regulation should be amended. We are specifically seeking comment on this issue.

Physical Environment (§ 482.41)

Currently, hospitals are required to meet the standards of the 2000 edition of the Life Safety Code (LSC), which is not the most recent edition. Many accrediting bodies, as well as state and local jurisdictions, require hospitals to comply with more recent versions, such as the 2003, 2006, or 2009 edition of the LSC. Complying with both the 2000 edition of the LSC, for Federal purposes, and a more recent edition, for accreditation or other purposes, can be challenging for hospitals when there are

inconsistencies between the two versions.

We expect the 2012 edition of the LSC to be released in Fall 2011. Based on the content of the 2012 edition, we will decide whether it or another more recent edition, is appropriate for incorporation into the regulations for hospitals and other affected providers and suppliers. Any regulatory changes would be addressed through separate notice-and-comment rulemaking. We are specifically seeking comment on this issue.

III. Collection of Information Requirements

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

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

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

According to CMS, there are about 4,900 hospitals (not including CAHs) that are certified by Medicare and/or Medicaid. We will use those figures to determine the burden for this rule. In addition, throughout this section, we estimate costs based on average hourly wages for different healthcare providers and attorneys. Unless indicated otherwise, we obtained these average hourly wages from the United States Bureau of Labor Statistics' ''May 2010 National Occupational Employment and Wage Estimates United States'' (*http://www.bls.gov/oes/current/oes_nat.htm* accessed on September 28, 2011). We also added 30 percent to the indicated average hourly wage to allow for overhead and fringe benefits.

A. ICRs Regarding Condition of Participation: Patient's Rights (§ 482.13)

Proposed § 482.13(g) would remove the current requirement for hospitals to notify CMS by telephone no later than the close of business the next business day following knowledge of a patient's death for patients who die when no seclusion has been used and the only restraints used on the patient were soft, non-rigid, cloth-like materials, which were applied exclusively to the patient's wrist(s). This requirement would include patients who died within 24 hours of having been removed from these types of restraints. In those cases, the hospital must report to CMS by recording in a log or other system the information required at proposed § 482.13(g)(2)(i) and (ii). We are proposing this change only for deaths where the patient died while either in soft two-point wrist(s) restraints or within 24 hours of having been removed from soft two-point wrist(s) restraints provided that: (a) There is no reason to believe the death was caused by those restraints, (b) that those were the only restraints used, and (c) that no seclusion was used.

We believe that we previously underestimated the burden and costs associated with the current reporting requirement. After discussions with other CMS staff, we now believe that this reporting would be done by a nurse rather than a clerical person and that there are substantially more deaths that occurred to patients while they were in soft, non-rigid, cloth-like material, which were applied exclusively to a patient's wrist(s), or within 24 hours of being removed from this type of restraints.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and would adjust for any burden reductions resulting from this provision once the current proposal is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

B. ICRs Regarding Condition of Participation: Nursing Services (§ 482.23)

The current hospital CoPs require that hospitals ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient (42 CFR 482.23(b)(4)). Proposed 482.23(b)(4) would allow those hospitals that have interdisciplinary care plans (ICPs) to have their nursing care plans developed and kept current as part of the hospital's ICPs. Based on our experience with hospitals, a nurse would develop and maintain the nursing care plan for each patient. The nurse would also be responsible for identifying the sections of each nursing care plan that needed to be integrated into the hospital's ICP and transferring that information into the ICP. Thus, allowing hospitals to include the nursing care plan in the ICP for each patient would save the nurse the time she or he is currently spending identifying and transferring information from the separate nursing care plan into the ICP and maintaining the separate nursing care plan.

In the currently approved OMB control number 0938–0328, we indicated that the creation and maintenance of a nursing care plan constituted a usual and customary business practice and did not assign a burden for this requirement in accordance with 5 CFR 1320.3(b)(2). Since completing that package, we have reconsidered our estimate of that analysis. While we continue to believe that creating and maintaining a health care plan for each patient is a usual and customary practice for hospitals, we do not believe that is usual and customary for hospitals to develop and maintain a separate nursing care plan when they also develop and maintain an ICP.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and would adjust for any burden reductions resulting from this provision once the current proposal is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

C. ICRs Regarding Condition of Participation: Medical Record Services (§ 482.24)

In the currently approved OMB control number 0938–0328, we indicated that most of the patient-related activities, such as authentication of verbal orders and using standing orders, constituted a usual and customary business practice and did not assign a burden for this requirement in accordance with 5 CFR 1320.3(b)(2). However, we have reconsidered our analysis. We believe that the authentication of verbal orders should be governed by state law and not mandated by the Federal government. In addition, while writing orders is generally a usual and customary business practice in hospitals, hospitals can also choose how those orders will be conveyed. We believe that some hospitals are not currently using

standing orders as often as they would choose to due to our CoPs. Therefore, by allowing authentication of verbal orders to be governed by state law and expanding the use of standing orders, we believe that these provisions would result in a burden reduction.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and would adjust for any burden reductions resulting from this provision once the current proposal is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

D. ICRs Regarding Condition of Participation: Infection Control (§ 482.42)

The current hospital CoPs require that ''the infection control officer or officers must maintain a log of incidents related to infections and communicable disease'' (42 CFR 482.42(a)(2)). We are proposing to eliminate this requirement for keeping a dedicated log of incidents related to infections and communicable diseases, proposing instead to allow hospitals flexibility in their approach to the tracking and surveillance of infections.

In the currently approved OMB control number 0938–0328, we did not assign a burden for creating and maintaining this log. However, we have reconsidered our analysis. We believe there are many alternatives available that present an even greater opportunity to monitor and analyze infection control activities than keeping a log as currently required by the CoPs. In addition, we believe that the log is a format that hospitals are using only because of the CMS requirement and that they are producing data in this fashion in addition to the format they are using for their own purposes. Thus, while identifying and monitoring infections that patient have during hospitalization would be usual and customary for hospitals, we believe that requiring hospitals to keep a log rather than decide how they could best keep track of this information is burdensome for hospitals.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and will adjust for any burden reductions resulting from this provision once the current proposal is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

E. ICRs Regarding Condition of Participation: Transplant Center Process Requirements—Organ Recovery and Receipt (§ 482.92)

We propose removing 482.92(a) entirely. The elimination of this section would remove the burden on the part of transplant centers by eliminating a requirement to review and compare blood type and other vital data before organ recovery takes place.

In the currently approved OMB control number 0938–1069, we indicated that the verification by the transplant hospital recovery physician when the recipient was known constituted a usual and customary business practice and did not assign a burden for this requirement in accordance with 5 CFR 1320.3(b)(2). However, since that PRA package was approved by OMB, several members of the transplant community have repeatedly told CMS that this verification was unnecessary and burdensome because OPOs already perform this type of verification prior to organ recovery in accordance with 486.344(d)(2)(ii). Therefore, we have reconsidered our estimate of the burden for this requirement.

We will be revising the current burden estimates for OMB control number 0938–0328 to reflect the burden estimated to be associated with the current regulations and would adjust for any burden reductions resulting from this provision once the current proposal is finalized. For a more detailed discussion of estimated burden and cost savings, please see the Regulatory Impact Analysis section of this rule.

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 Impacts

A. Regulatory Impact Analysis

1. Introduction

We have examined the impacts of this rulemaking as required by Executive Orders 12866 (September 1993) and 13563 (January 2011). 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, reducing costs, harmonizing rules, and promoting flexibility. A Regulatory Impact Analysis (RIA) must be prepared for rules with economically significant effects ($100 million or more in any one year). This proposed rule is an ''economically'' significant regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has reviewed this proposed rule.

2. Statement of Need

In Executive Order 13563, the President recognized the importance of a streamlined, effective, efficient regulatory framework designed to promote economic growth, innovation, job-creation, and competitiveness. To achieve a more robust and effective regulatory framework, the President has directed each executive agency to establish a plan for ongoing retrospective review of existing significant regulations to identify those rules that can be eliminated as obsolete, unnecessary, burdensome, or counterproductive or that can be modified to be more effective, efficient, flexible, and streamlined. Consistent with this directive, CMS has conducted a retrospective review of the conditions of participation it imposes on hospitals to remove or revise obsolete, unnecessary, or burdensome provisions. The goal of the retrospective review is to identify opportunities reduce system costs by removing obsolete or burdensome requirements while maintaining patient care and outcomes.

CMS had not reviewed the entire set of Conditions of Participation for Hospitals in many years. These requirements had grown over time and, while often revised, had not been subject to a complete review. CMS staff as well as CMS stakeholders, including TJC, the American Medical Association, the AHA, and many others, had identified problematic requirements over the years. Accordingly, we decided to conduct a retrospective review of the conditions of participation imposed on hospitals and to remove or revise obsolete, unnecessary, or burdensome provisions, and to increase regulatory flexibility while identifying and adding opportunities to improve patient care and outcomes. We analyzed all potential reforms and revisions of the CoPs for both the costs and the benefits that they would bring to hospitals and CAHs,

Based on our analysis, we decided to pursue those regulatory revisions that would reflect the substantial advances that have been made in healthcare delivery and that would benefit hospitals and CAHs through cost savings.

3. Summary of Impacts

These proposed reductions in process and procedure requirements will facilitate redirection of staff resources to higher priorities with greater benefit both to patients directly and through the increased flexibility that institutions will have to reengineer internal processes. We present a summary of these cost reducing changes in Table 2.

TABLE 1—SECTION-BY-SECTION SUMMARY OF COST SAVINGS TO HOSPITALS AND CAHS

[Entries rounded to nearest $100K if under $50M and to nearest $10M if higher]

Regulatory area	Section	Annual savings ($K)
Patient's Rights—Death Notice Soft Restraints	482.13	9,900
Medical Staff	482.22	330,000
Nursing Services—Care Plan	482.23	110,000
Medical Record Services—Authentication	482.24	80,000
Medical Record Services—Standing Orders	482.24	90,000
Infection Control—Eliminate Log	482.42	6,600
Outpatient Services	482.54	300,000
Transplant Organ recovery	482.92	200
CAH Direct Services	485.635	15,800
Total	.....	942,500

Some of these savings come simply from reductions in process requirements and reporting. The changes in the area of Medical staffing and several other areas would allow hospitals more flexibility in hiring and staffing decisions, including use of part-time and contract staff, to provide patient services efficiently and effectively. Total national hospital spending is about nine hundred billion dollars a year and about half of this is spent on staff compensation (source: AHA Hospital Statistics). Thus, the potential magnitude of the efficiencies that could be achieved is very large.

Clearly, the amount of savings actually realized through these reforms will depend on the individual decisions of about 6,100 hospitals (including CAHs), over time. We cannot predict the extent or speed of these elective changes. Other factors, such as impending physician shortages and the growing use of other practitioners to perform many physician functions will play a role as will State decisions on laws delineating scope of practice.

Furthermore, for the requirements that we propose to modify or delete, we are not aware of any information suggesting that the change we propose would create consequential risks for patients. In other words, we do not believe that any requirement we propose to eliminate has saved lives in recent decades.

We welcome comments on ways to better estimate the likely effects of these reforms within the broader array of influences on delivery of care.

4. Anticipated Impacts

There are about 4,900 hospitals and 1,200 CAHs that are certified by Medicare and/or Medicaid. We use these figures to estimate the potential impacts of this proposed rule. According to CMS' Center for Medicaid, Children's Health Insurance Program (CHIP), and Survey and Certification (CMCS), for fiscal year (FY) 2010, TJC accredited 3,839 hospitals and 365 CAHs. For TJC-accredited hospitals and CAHs we will use the figures of 3,800 and 400, respectively. For non TJC-accredited hospitals and CAHs, we will use the figures of 1,100 and 800, respectively. In addition, we use the following average hourly wages for nurses and physicians respectively: $45 and $124 (BLS Wage Data by Area and Occupation, including both hourly wages and fringe benefits, at *http://www.bls.gov/bls/blswage.htm* and *http://www.bls.gov/ncs/ect/*). The analysis below overlaps with the Collection of Information Requirements section for many individual items. That section contains more technical and legal detail as appropriate under the Paperwork Reduction Act, but that is not necessary or appropriate in a Regulatory Impact Analysis. Readers may wish to consult both sections on some topics.

Death Notices for Soft Restraints (Patient's Rights § 482.13)

We propose to remove the current requirement for hospitals to notify CMS by telephone no later than the close of business the next business day following knowledge of a patient's death for patients who die when no seclusion has been used and the only restraints used on the patient were soft, non-rigid, cloth-like materials, which were applied exclusively to the patient's wrists. Reporting would also be removed for patients who died within 24 hours of having been removed from these types of restraints.

We estimate that full reporting of all such instances would result in 882,000 occurrences. This is much greater than the assumption that originally established this reporting requirement in the final rule (71 FR 71425). However, since the requirements have come into effect, we believe our initial estimate was low. Also, the assumption in the 2006 final rule was that these functions would be carried out by a clerical person. Based on our experience with hospitals, this assumption is incorrect. A registered nurse would be the more appropriate staff member to make the call and to enter the information into a patient's medical record. The difference between the average hourly wage for a clerical person and a registered nurse ($18.88 per hour versus $45 per hour) would account for a significant discrepancy in estimated burden between the 2006 final rule and this proposed rule. Similar to the 2006 rule, we still estimate that it would take about fifteen minutes (or .25 hours) to comply with this requirement for each occurrence. The estimate of the time is also based on our experiences with hospitals as well as feedback from stakeholders that indicates that this estimate is reasonable. Therefore, we estimate that this reduction in burden would reduce

a hospital's burden hours by 45 hours each year valued at $45 per hour for an annual savings of $2,025. Thus, we estimate that for all 4,900 hospitals this would result in a savings of about $9,922,500.

Medical Staff (§ 482.22)

Our changes and clarifications regarding medical staff and privileging would allow hospitals to substitute and rearrange actual delivery of care. In particular, use of Advanced Practice Nurse Practitioners (APRNs) and Physician Assistants (PAs) in lieu of higher-paid physicians could provide immediate savings to hospitals. We have no precise basis for calculating potential savings, which in any event depend on future staffing and management decisions, but they are very substantial. For purposes of this analysis we have reached an estimate of $330 million using the following assumptions:

- All hospitals are able, under State scope of practice laws (that is, 4,900 hospitals), and one third of these are willing (that is, 1,617), to make such medical staff substitutions;
- There are on average 7,000 inpatient hospital stays per hospital per year (from AHA Hospital Statistics);
- The average hospital stay is about 5 days (per AHA statistics);
- On average, each patient receives approximately 75 minutes (1.25 hours) of a physician's time (for example, in-person visits/assessments, including patient and family education; review of patient lab and other diagnostic test results; documentation of orders, progress notes, and other entries in the medical record; performance of minor procedures; and discussion of the patient's condition with other staff) during an average 5-day stay;
- At a minimum, 33 percent of this physician per patient time would now be covered by nonphysician practitioners (for example, APRNs and PAs); and
- There is an average salary difference of $71 an hour between physicians and these practitioners.

The resulting savings estimate of about $330 million annually (1,617 hospitals × 7,000 inpatient hospital stays × 1.25 hours of physician/nonphysician practitioner time × $71 per hourly wage difference × 33 percent of physician time with patients covered by nonphysician practitioners) could obviously be much higher or lower if any of the parameters above changed. Additionally, we have restricted our estimates to inpatient hospital stays and we did not include a discussion of the approximately 620,000,000 annual hospital outpatient visits (AHA Hospital Statistics) and the impact that the proposed changes could have on staffing costs for hospitals in light of this number. Thus, many reasonable variations of our assumptions would lead to a similar magnitude of savings. We welcome comments on these estimates and on ways to improve them.

Nursing Services Care Plan (§ 482.23)

The current hospital CoPs require that hospitals ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. Our proposal would allow those hospitals that have interdisciplinary care plans (ICPs) to have their nursing care plans developed and kept current as part of the hospital's ICPs.

Based on our experience with hospitals, a nurse would develop and maintain the nursing care plan for each patient. The nurse would also be responsible for identifying the sections of each nursing care plan that needed to be integrated into the hospital's ICP and transferring that information into the ICP. Thus, allowing hospitals to include the nursing care plan in the ICP for each patient would save the nurse the time he or she is currently spending identifying and transferring information from the separate nursing care plan into the ICP and maintaining the separate nursing care plan. We believe that many hospitals have already developed methods for eliminating this time-wasting step, particularly those hospitals that have largely implemented an electronic health records system. Assuming that about 60 percent have done so, this reform would only affect roughly 16 million patients (40 percent of 40 million admissions).

We estimate that allowing a hospital to use only the ICP would save the nurse an average of nine minutes or 0.15 hours and would affect 16,000,000 patients. Thus, the proposed provision would result in a reduction of 2,400,000 burden hours valued at $45 per hour for a savings of $108,000,000.

Medical Record Services—Authentication and Standing Orders (§ 482.24)

We are proposing to revise the Medical Records CoP to eliminate the requirement for authentication of verbal orders within 48 hours if no State law specifying a timeframe exists. Since we believe that very few States have authentication timeframe requirements, we do not believe that the few States that may have such requirements would impact the potential savings we are estimating here. We are also proposing to make permanent the temporary provision (5-year Sunset provision due to expire early 2012) that allows for orders to be authenticated by another practitioner who is responsible for the care of the patient and who, in accordance with hospital policy State law, is authorized to write orders.

We believe that this provision would result in a burden reduction. We would expect a registered nurse or compliance officer to be responsible for checking medical records and flagging orders needing authentication, particularly those verbal orders nearing the current 48-hr timeframe. Based on our experience with hospitals and feedback from stakeholders on this issue, we believe that hospitals will save one hour of a nurse's time every day for 365 burden hours for each hospital annually. For all 4,900 hospitals, this would result in a reduction of 1,788,500 burden hours, valued at $45 per hour for a savings of $80,482,500.

We are also proposing to add new provisions to allow hospitals to use pre-printed and electronic standing orders, order sets, and protocols for patient orders if the hospital ensures that these orders: have been reviewed and approved by the medical staff and nursing and pharmacy leadership; are consistent with nationally recognized guidelines; are reviewed periodically and regularly by medical staff and nursing and pharmacy leadership; and are dated, timed, and authenticated by a practitioner who is responsible for the care of the patient and who is authorized to write orders by hospital policy in accordance with State law. In addition, we proposed to allow for drugs and biologicals to be prepared and administered on the orders of other practitioners if they are acting in accordance with State law and scope of practice and the hospital has granted them the privileges to do so.

The use of standing orders, order sets, and protocols reduces a hospital's burden in several ways. Initially, it saves the physician or other practitioner the time it takes to write out the orders. It also saves the physician the time it would take to go back to the chart or call a nurse with a verbal order if the physician forgets a particular order. The nurses also save time when standing orders are used. The orders are more legible so there is less time interpreting and calling physicians for verification. Nurses also need to call physicians less frequently when there is a change in the patient's condition or they feel there needs to be a change in the care the patient is receiving. Patients also benefit from standing orders because there would be less delay in the delivery of needed care to a patient. Thus, we believe that expanding the use of

standing orders would significantly reduce the hospital's burden.

Based on our experience with hospitals and on stakeholder feedback regarding the issue of standing orders, we estimate that these provisions would affect 13 million patients or roughly one-third of hospital admissions. We also estimate that using standing orders would result in a burden reduction of an average of 4 minutes or 0.07 hours for each of these patients. Thus, expanding the use of standing orders would result in a reduction of 700,000 burden hours valued at $124 per hour for a savings of $86,800,000.

Outpatient Services (§ 482.54)

Our proposed liberalization of outpatient services supervision will permit large savings. Under the existing Condition of Participation, only one person may direct outpatient services. Similar to our estimates for medical staff savings, what savings hospitals may realize would depend largely on their future decisions, and cannot be predicted with any precision. For purposes of estimation, we have developed an estimate that illustrates the potential. Under this estimate, we assume that two-thirds of the hours eliminated would represent net savings, since existing directors obviously perform significant coordination functions that would have to be performed however the work is organized. To be more specific, potential savings are based on the following:

- Two-thirds of hospitals elected to redirect these overall director functions (3,267 hospitals);
- On average, each position represents 2,000 hours per year;
- Only two-thirds of the hours eliminated represented net savings; and
- Compensation averages about $70 an hour.

Based on these assumptions, this reform would produce $305 million annually in staff savings (3,267 hospitals × 2,000 hours × ⅔ × $70 per hour). A similar result would be obtained if four-fifths of hospitals redirected these functions, but the net hours saved were only a little more than half of the current hours.

Transplant Organ Recovery (§ 482.92)

We propose removing the current blood typing requirement entirely. The elimination of this section would remove transplant center burden by eliminating a requirement to review and compare blood type and other vital data before organ recovery takes place. The OPOs already perform this type of verification prior to organ recovery. In addition, since publication of the existing rule, the transplant community has repeatedly told CMS that the verification that we propose to delete is burdensome and unnecessary.

Under the current requirements for this situation, the OPO performs a verification before organ recovery, the surgeon working for the transplant center performs a verification before organ recovery, and the transplant center surgeon performs another verification before the organ is transplanted. Under the proposed requirement, the OPO performs a verification before organ recovery and the transplant center surgeon performs a verification before the organ is transplanted. We would eliminate the verification that is conducted by the staff working on behalf of the transplant center that must occur prior to organ recovery. In addition, the responsibility for maintaining these records is very unclear, and has caused conflict between surgeons, transplant centers, and the hospitals where the organ recoveries are performed. Elimination of the extra verification step removes this source of conflict and confusion.

Between July 1, 2009 and June 30, 2010, the United States saw 2,293 heart and 1,699 lung transplants. During the same time frame, there were also 16,679 transplants for kidneys, 6,301 for livers, and 371 for pancreases. (Scientific Registry of Transplant Recipients (SRTR) *http://srtr.org/csr/current/nats.aspx,* date last accessed 6/9/10). Most organ recoveries for heart and lung transplants are conducted by surgeons working for their own transplant centers. By contrast, in the case of kidneys, livers, and pancreases, these organs are typically recovered by surgeons who are on-call for an OPO and who are not also working for, or privileged at, the same transplant center where the organ is delivered. For purposes of this analysis, we assume that 25 percent of kidney, liver and pancreas organ recoveries are conducted by surgeons who are working for the transplant centers. It is in this small percentage of transplant cases, roughly 5,800, together with the total number of heart and lung transplants, where the requirement for an additional verification has resulted in overlapping and burdensome requirements. For the purpose of analysis, we have assumed that conducting the verification and filing the corresponding paperwork would take 8 minutes and that there are 9,972 transplant cases. We therefore conclude that removing the duplicative verification requirement will result in an annual savings of 1,305 burden hours valued at $124 per hour for a monetary savings of $161,820.

Infection Control Log (§ 484.42)

We are proposing to eliminate a requirement for keeping a dedicated log of incidents related to infections and communicable diseases, proposing instead to allow hospitals flexibility in their approach to the tracking and surveillance of infections. We believe the changes we are proposing overall would result in the more efficient use of time.

We believe that the current log requirement requires roughly 30 hours annually of a nurse's time per hospital (*i.e.,* an average of 600 to 900 log entries per year and 2–3 minutes per entry). Thus, for all 4,900 hospitals this change would result in a savings of 147,000 burden hours valued at $45 per hour for a savings of $6,615,000.

CAH Provision of Services (§ 485.635)

Our proposed removal of the ''direct services'' requirement imposed on CAHs would eliminate the requirement that certain services be provided only by employees and not through contractual arrangements with entities such as community physicians, laboratories, or radiology services. Opportunities may be limited because CAHS are both small and overwhelmingly located in rural areas where there may not be realistic alternatives to direct hiring. We estimate that this could produce savings of approximately one tenth of one full-time equivalent staff person in payroll savings on average, at an average compensation cost of $66, for a total of about $16 million saved annually across all 1,200 CAHs. Savings might be considerably larger, and we welcome information and data on this question.

5. Alternatives Considered

From within the entire body of conditions of participation, the most serious candidates for reform were those identified by stakeholders, by recent research, or by experts as unusually burdensome if not unchanged. This subset of the universe of standards is the focus of this proposed rule. We welcome comments on whether we properly selected the best candidates for change, and will consider suggestions for additional reform candidates from the entire body of conditions of participation for hospitals and CAHs.

A second set of alternatives arises because there are obviously various ways to draft each requirement. For each requirement that we have proposed for deletion or modification there are a number of possible options, including making no change, making the change

we propose, and in some but not all cases making some in-between change. Most standards have an ''either-or'' nature, but we welcome comments on possible variations. There is a final set of alternatives revolving around entirely different methods of achieving potential benefits, such as incentive payments through Medicare or other health plans to high-performing institutions, or publishing quality scores to make hospital strengths and weaknesses transparent to both the public at large and to practitioners. A number of such reforms are underway. Likewise, there are alternatives such as technical assistance through Quality Improvement Organizations (QIOs) funded by CMS, also underway under the latest QIO contracts. We welcome comments on such alternatives.

6. Uncertainty

Our estimates of the effects of this regulation are subject to significant uncertainty. While CMS is confident that these reforms would provide flexibilities to hospitals that would yield cost savings, we are uncertain about the magnitude of these effects. In addition, as we previously explained, we do not believe that any requirement we propose to eliminate achieved any consequential improvements in patient safety. Thus, we are confident that the rule would yield net benefits. In this analysis we provided some illustrative estimates to suggest the potential savings these reforms could achieve under certain assumptions. We welcome comments on ways to better estimate the likely effects of these reforms.

7. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), we have prepared an accounting statement. As previously explained, achieving the full scope of potential savings will depend on future decisions by hospitals, by State regulators, and others. Many other factors will influence long-term results. We believe, however, that likely savings and benefits will reach many billions of dollars. Our primary estimate of the net savings to hospitals from reductions in regulatory requirements that we can quantify at this time, offset by increases in other regulatory costs, are approximately $940 million a year. We welcome comments on both the overall estimate and its components.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND SAVINGS

[$ in millions]

Category	Primary estimate	Units		
		Year dollars	Discount rate	Period covered
Benefits	None			
Costs				
	−$940	2012	7%	2012–16
Annualized Monetized reductions in Costs	$940	2012	3%	2012–16
Transfers	None			

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), as modified by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), requires agencies to determine whether proposed or final rules would have a ''significant economic impact on a substantial number of small entities'' and, if so, to prepare a Regulatory Flexibility Analysis and to identify in the notice of proposed rulemaking or final rulemaking any regulatory options that could mitigate the impact of the proposed regulation on small businesses. For purposes of the RFA, small entities include businesses that are small as determined by size standards issued by the Small Business Administration (SBA), nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. The SBA size threshold for ''small entity'' hospitals is $34.5 million or less in annual revenues. Also, all non-profit hospitals are small entities under the RFA. About three-fifths of all hospitals (including CAHs) are non-profit and about one-third (many overlapping) have annual revenues below the SBA size threshold. Because the great majority qualifies as ''small entities,'' HHS policy for many years has been to treat all hospitals as small entities deserving protection under the RFA. Although the overall magnitude of the paperwork, staffing, and related cost reductions to hospitals and CAHs proposed under this rule is economically significant, these savings are likely to be only about one percent of total hospital costs. Total national inpatient hospital spending is approximately nine hundred billion dollars a year, or an average of about $150 million per hospital, and our primary estimate of the net effect of these proposals on reducing hospital costs is only about $940 million annually (although potentially far higher). This is an average of slightly over $150,000 in savings on average for the 6,100 hospitals (including CAHs) that are regulated through the Conditions of Participation. Under HHS guidelines for Regulatory Flexibility Analysis, actions that do not negatively affect costs or revenues by about 3 to 5 percent a year are not economically significant. We believe that no hospitals of any size will be negatively affected. Accordingly, we have determined that this proposed rule would not have a significant economic impact on a substantial number of small entities, and that an Initial Regulatory Flexibility Analysis is not required. Notwithstanding this conclusion, we believe that this RIA and the preamble as a whole meet the requirements of the RFA for such an analysis.

In addition, section 1102(b) of the Social Security 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 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 do not believe a regulatory impact analysis is required here for the same reasons previously

described and because, in addition, our proposals are particularly cost-reducing for the smallest hospitals, including especially CAHs (which in most cases have no more than 25 beds).

C. Unfunded Mandates Reform Act of 1995

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates on State, local, or Tribal governments in the aggregate, or on the private sector, require spending in any one year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently about $136 million. This proposed rule would eliminate or reform existing requirements and would allow hospitals and CAHs to achieve substantial savings through staffing reforms. Accordingly, no analysis under UMRA is required.

D. Federalism

Executive Order 13132 on Federalism establishes certain requirements that an agency must meet when it publishes 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. We have determined that this proposed rule would not significantly affect the rights, roles, or responsibilities of the States. This proposed rule would not impose substantial direct requirement costs on State or local governments, preempt State law, or otherwise implicate federalism. It does, however, facilitate the ability of States to reform their scope of practice laws without Federal requirements reducing the effectiveness of such reforms. We understand that about half of the States are considering such reforms, and we support such efforts.

VI. Regulations Text

List of Subjects

42 CFR Part 482

Grant programs—Health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs—Health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

1. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102, 1871 and 1881 of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr), unless otherwise noted.

Subpart B—Administration

2. Section 482.12 is amended by revising the introductory text to read as follows:

§ 482.12 Condition of participation: Governing body.

There must be an effective governing body that is legally responsible for the conduct of the hospital. If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

* * * * *

§ 482.13 Condition of participation: Patient's rights.

3. Section 482.13 is amended by—

a. Revising paragraphs (g)(1), (g)(2), and (g)(3).

b. Adding a new paragraph (g)(4).

The revisions and additions read as follows:

§ 482.13 Condition of participation: Patient's rights.

* * * * *

(g) * * *

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. ''Reasonable to assume'' in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must report to CMS by recording in a log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints; and

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) For deaths described in paragraphs (g)(1) and (g)(2) of this section, staff must document in the patient's medical record the date and time the death was reported to CMS.

(4) For deaths described in paragraph (g)(2) of this section, entries into the log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient;

(ii) Each entry must document the patient's name, date of birth, date of death, attending physician's name, medical record number, and primary diagnosis(es); and

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

Subpart C—Basic Hospital Functions

4. Section 482.22 is amended by—

a. Revising the introductory paragraph.

b. Revising paragraph (a) introductory text.

a. Adding a new paragraph (a)(5).

b. Revising (b)(3).

The revisions and additions read as follows:

§ 482.22 Condition of participation: Medical staff.

The hospital must have an organized medical staff that operates under bylaws approved by the governing body and is responsible for the quality of medical care provided to patients by the hospital.

(a) *Standard: Composition of the medical staff.* The medical staff must be composed of doctors of medicine or osteopathy and, in accordance with State law, may also be composed of other practitioners appointed by the governing body.

* * * * *

(5) The medical staff must examine the credentials of candidates applying for practice privileges and medical staff membership within the hospital, as well as the credentials of practitioners applying only for hospital practice privileges, and make recommendations to the governing body for the

appointment of these candidates and the approval of these privileges in accordance with State law and hospital policies and procedures. A physician or nonphysician practitioner who has been granted practice privileges by the governing body for practice activities authorized within his or her State scope of practice is subject to all medical staff requirements contained in this section.

(b) * * *

(3) The responsibility for organization and conduct of the medical staff must be assigned only to:

(i) An individual doctor of medicine or osteopathy,

(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located; or

(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

* * * * *

5. Section 482.23 is amended by—

a. Revising paragraph (b)(4).

b. Revising paragraph (c).

The revisions and additions read as follows:

§ 482.23 Condition of participation: Nursing services.

* * * * *

(b) * * *

(4) The hospital must ensure that the nursing staff develops, and keeps current, a nursing care plan for each patient. The nursing care plan may be part of an interdisciplinary care plan.

* * * * *

(c) *Standard: Preparation and administration of drugs.* (1) Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under § 482.12(c), and accepted standards of practice.

(i) Drugs and biologicals may be prepared and administered on the orders of other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law, including scope of practice laws, and only if the hospital has granted them privileges to do so.

(ii) Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of § 482.24(c)(3).

(2) All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

(3) With the exception of influenza and pneumococcal polysaccharide vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders in accordance with State law and hospital policy, and who is responsible for the care of the patient as specified under § 482.12(c).

(i) If verbal orders are used, they are to be used infrequently.

(ii) When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.

(iii) Orders for drugs and biologicals may be documented and signed by other practitioners not specified under § 482.12(c) only if such practitioners are acting in accordance with State law and scope of practice and only if the hospital has granted them privileges to do so.

(4) Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

(5) There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

(6) The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.

(i) If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:

(A) Assure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration;

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s);

(C) Instruct the patient (or the patient's caregiver/support person where appropriate) in the safe and accurate administration of the specified medication(s);

(D) Ensure the security of the medication(s) for each patient; and

(E) Document the administration of each medication in the patient's medical record.

(ii) If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital, then the hospital must have policies and procedures in place to:

(A) Assure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital;

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s), and also determine if the patient (or the patient's caregiver/support person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s);

(C) Identify the specified medication(s) and visually evaluate the medication(s)for integrity;

(D) Ensure the security of the medication(s) for each patient; and

(E) Document the administration of each medication in the patient's medical record.

6. Section 482.24 is amended by—

a. Removing paragraphs (c)(1)(i), (c)(1)(ii), and (c)(1)(iii).

b. Redesignating (c)(2) as (c)(4).

c. Adding a new paragraph (c)(2).

d. Adding a new paragraph (c)(3).

The revisions and additions read as follows:

§ 482.24 Condition of participation: Medical record services.

* * * * *

(c) * * *

(2) All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or another practitioner who is responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.

(3) Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) Establishes that such orders and protocols have been reviewed and approved by the medical staff in consultation with the hospital's nursing and pharmacy leadership;

(ii) Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;

(iii) Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff, in consultation with the hospital's

nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and protocols; and

(iv) Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient as specified under § 482.12(c) and authorized to write orders by hospital policy in accordance with State law.

* * * * *

7. In § 482.25 paragraph (b)(6) is revised to read as follows:

§ 482.25 Condition of participation: Pharmaceutical services.

* * * * *

(b) * * *

(6) Drug administration errors, adverse drug reactions, and incompatibilities must be immediately reported to the attending physician and, if appropriate, to the hospital's quality assessment and performance improvement program.

* * * * *

8. Section 482.42 is amended by revising paragraph (a) and (b)(1) to read as follows:

§ 482.42 Condition of participation: Infection control.

* * * * *

(a) *Standard: Organization and policies.* A person or persons must be designated as infection control officer or officers to develop and implement policies governing control of infections and communicable diseases. The infection control officer or officers must develop a system for identifying, reporting, investigating, and controlling infections and communicable diseases of patients and personnel.

* * * * *

(b) * * *

(1) Ensure that the hospital-wide quality assessment and performance improvement (QAPI) program and training programs address problems identified by the infection control officer or officers; and

* * * * *

Subpart D—Optional Hospital Services

9. Section 482.54 is amended by revising paragraph (b) to read as follows:

§ 482.54 Condition of participation: Outpatient services.

* * * * *

(b) *Standard: Personnel.* The hospital must—

(1) Assign one or more individuals to be responsible for outpatient services.

(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

Subpart E—Requirements for Specialty Hospitals

§ 482.92 [Amended]

10. Section 482.92 is amended by—

a. Removing paragraph (a).

b. Redesignating paragraphs (b) and (c) as (a) and (b) respectively.

PART 485—CONDITIONS OF PARTICIPATION SPECIALIZED PROVIDERS

11. The authority citation for part 485 continues to read as follows:

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

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

§ 485.602 [Removed]

12. Section 485.602 is removed.

13. Section 485.604(a) is revised to read as follows:

§ 485.604 Personnel qualifications.

* * * * *

(a) *Clinical nurse specialist.* A clinical nurse specialist must be a person who—

(1) Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and

(2) Holds an advanced degree in a defined clinical area of nursing from an accredited educational institution.

* * * * *

14. Section 485.635(b) is revised to read as follows:

§ 485.635 Condition of participation: Provision of services.

* * * * *

(b) *Standard: Patient services. (1) General:* The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) *Laboratory services.* The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose;

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) *Radiology services.* Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.

(4) *Emergency procedures.* In accordance with requirements of § 485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness.

15. Section 485.639 is amended by revising the introductory text to read as follows:

§ 485.639 Condition of participation: Surgical services.

If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under paragraph (a) of this section.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program) (Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: September 30, 2011.

Donald M. Berwick,

Administrator, Centers for Medicare & Medicaid Services.

Approved: October 6, 2011.

Kathleen Sebelius,

Secretary. Department of Health and Human Services.

[FR Doc. 2011–27175 Filed 10–18–11; 11:15 am]

BILLING CODE 4120–01–P