

Medicare and Medicaid Programs: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care
[CMS-3346-F, CMS-3334-F, CMS 3295-F]

Summary of Final Rules

The Centers for Medicare & Medicaid Services (CMS) published together in the September 30, 2019 *Federal Register* (84 FR 51732) three final rules. The first rule addresses certain Medicare regulations identified by CMS as unnecessary, obsolete, or excessively burdensome on a subset of health care providers and suppliers. The second rule extends updated fire safety requirements to certain renal dialysis facilities. The third rule revises certain hospital and Critical Access Hospital (CAH) conditions of participation (CoPs), including those focused on infection control, antibiotic use, and antidiscrimination. Unless otherwise noted, the rules are effective November 29, 2019.

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I. Final Rule: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

A. Religious Nonmedical Health Care Institutions (RNHCIs) - Discharge Planning

Section 1861(ss)(1) of the Social Security Act (“the Act”), defines a RNHCI and the requirements that must be met to be eligible for Medicare participation. A RNHCI is a facility that provides nonmedical health care items and services to people who need hospital or skilled nursing facility care, but for whom that care would not be consistent with their religious beliefs. An RNHCI does not provide medical screenings, examination, diagnosis, prognosis, or treatment to a beneficiary.

CMS finalizes its proposal to revise the Conditions of Participation (CoPs) at §403.736(a), requiring an evaluation, and §403.736(b), requiring a discharge plan.

CMS removes the current requirements at §403.736(a) and (b) and finalizes at §403.736(a), that RNHCIs must have a discharge planning process that applies to all patients. The RNHCI must have policies that address their discharge processes, including the determination that a patient does or does not require discharge instructions. If the RNHCI’s patient assessment does not indicate a need for a discharge plan, the beneficiary or their legal representative may request a discharge plan and the RNHCI must comply with this request. Surveyors will be expected to review the RNHCI policies and confirm that either the existence or lack of discharge instructions is consistent with the RNHCI’s policies.

CMS notes that the majority of commenters strongly supported this proposal; no comments opposed the proposal. In response to a comment about enforcing this policy, CMS states that RNHCIs are monitored for compliance with the CoPs and this process adequately ensures RNHCIs are correctly interpreting and following requirements.

Regulatory Impact Analysis

Recent claims data indicates there were a combined annual total of 619 beneficiaries that stayed in the 18 Medicare-certified RNHCIs. CMS estimates the information collection requirements (ICRs) related to the discharge planning would be reduced by \$22,903.

B. Ambulatory Surgical Centers (ASCs)

42 CFR 416.2 defines an ASC as any distinct entity that operates exclusively to provide surgical services to patients not requiring hospitalization and the expected duration of services would not exceed 24 hours following an admission. Surgical services are primarily elective, non-life-threatening procedures that can be safely performed in an ambulatory setting. The Secretary is responsible for ensuring that Conditions for Coverage (CfCs) protect the health and safety of all patients treated in an ASC. As of May 2017, there were 5,557 Medicare participating ASCs.

1. Governing Body and Management; Hospitalization Requirements (§416.41(b)(3)(i) and (ii)) Section 416.41(b) describes the patient hospitalization procedures that ASCs must have in order to participate in Medicare. Section 416.41(b)(1) states that ASCs must have an effective procedure for the immediate transfer to a hospital for patients requiring emergency medical care that surpasses the capabilities of the ASC. Sections 416.41(b)(3)(i) and (ii) require ASCs to have written transfer agreements with a hospital that meets Medicare requirements or ensure all physicians performing surgeries in the ASC have admitting privileges in a hospital that meets Medicare requirements.

CMS proposed to remove the requirements at §416.41(b)(3) for a written hospital agreement or hospital physician admitting privileges. The requirements in §416.41(b)(1) and (2) would still apply and an ASC would be required to have an effective procedure for the immediate transfer to a hospital of patients requiring emergency medical care beyond the capabilities of the ASC and that the hospital must be a local hospital that meets the requirements for payment for emergency services.

Commenters were split between supporters and opponents of the proposal: ASCs supported the removal of the transfer agreement and hospitals were opposed to the removal of the transfer agreement. Commenters in support of the proposal stated the transfer agreement is unnecessary and burdensome for several reasons including the small number of patient transfers and administrative paperwork. In addition, the Emergency Medical Treatment and Labor Act (EMTALA) addresses emergency transfers from an ASC to a nearby hospital. Comments opposing removal of the written hospital transfer stated that transfer agreements have the potential to ensure there is a plan for emergencies and that both the ASC and hospitals communicate with each other. One commenter suggested that ASCs should periodically provide local hospitals with a written notice informing them of the types of patients that may need care beyond the capacity of the ASC.

CMS agrees with commenters that communication between ASCs and hospitals is important but it does not think a mandated written transfer agreement is a necessary method to ensure this communication. After considering the commenter's suggestion, CMS revises its proposal and finalizes at §416.41(b)(3) to require the ASC to periodically provide the local hospital with written notice of its operation and patient population served. CMS notes that a written notice could include details of the procedures performed in the ASC. CMS states that "periodically" is similar to the reappraisal requirement for the medical staff privileges in ASCs located at §416.45(b). CMS still encourages written transfer agreements and prior preparations be in place for patient transfers in the event of an emergency.

2. Patient Admission, Assessment, and Discharge (§416.52(a)(1), (2), (3), and (4))

Section 416.52(a) requires ASCs to ensure that a physician or other qualified practitioner provide a comprehensive medical history and physical assessment completed not more than 30 days before the date of the surgery.

CMS proposed to remove the requirements at §416.52(a)(1) and replace them with requirements that defer to the facility's established policies for pre-surgical medical history and physical examination (including any associated testing) and the operating physician's clinical judgment to

ensure each patient receives the appropriate pre-surgical assessment. Specifically, CMS would require that the facility's policy must:

- Include the timeframe for the medical history and physical examination to be completed prior to surgery;
- At a minimum address the following factors: patient age, diagnosis, type and number of procedures to be performed, known comorbidities, and the planned anesthesia level; and
- Follow nationally recognized standards of practice and guidelines, and applicable state and local health and safety laws.

CMS would retain the requirements at §416.52(a)(2), (3) and (4) that the physician performing the surgery or other qualified practitioner perform a pre-surgical assessment for each patient that includes documentation of any allergies to drugs and biologicals and also retain the requirement that any documentation related to the history and physical examination be placed in the patient's medical record prior to the surgical procedure.

The majority of commenters supported the proposal. A few commenters suggested CMS should retain the H&P requirements but allow the ASC the discretion to determine the timeframe for the H&P prior to surgery. One commenter was concerned that the proposed regulation text in §416.52(a)(1)(iii) stating that the ASC policy must "follow" nationally recognized standards of practice and guidelines could be problematic for ASCs. The commenter was concerned that this could be interpreted as requiring ASCs to "adhere" to national guidelines that are not delineated instead of determining the best clinical practices for patients.

In response to a comment about accreditation organizations' (AOs) standards, CMS notes that AOs may choose to retain any or all of the requirements removed in this final rule. AOs may choose to exceed CMS requirements as long as they do not conflict with any CMS requirement.

CMS finalizes its proposals with a modification at §416.52(a)(1)(iii) to state that the ASC policy must be based on nationally recognized standards of practice and any applicable state and local health and safety laws.

3. Medical Records (§416.47)

Section §416.47 requires ASCs to maintain complete, comprehensive, and accurate medical records to ensure adequate patient care. To conform to the proposed changes to the medical history and physical examination requirements at §416.52(a), CMS proposed to revise the requirements at §416.47(b)(2) that state "Significant medical history and results of physical examination", by adding "as applicable". CMS did not receive any comments on this proposal and it finalizes this change to the medical records.

4. Regulatory Impact Analysis

As of May 2017, there were 5,557 Medicare-participating ASCs. CMS estimates the savings for removing the transfer agreement or admitting privilege requirement at less than \$10,000 but notes that there are approximately twenty ASCs that do not meet the transfer agreement or admitting privileges requirements and will benefit from this proposal.

CMS discusses the limitations in estimating the savings attributed to removing the requirements for a comprehensive history and physical examination within 30 days prior to surgery for ASCs and for its corresponding proposal for hospital outpatient surgeries. CMS notes it does not know what medical specialty societies, ASC governing bodies, hospital governing bodies, or accreditation bodies will recommend instead of the current requirements. CMS believes this change will reduce administrative burden by decreasing the time that ASC personnel spend to obtain the necessary information, reduce unnecessary examinations, and reduce the time to prepare patients for surgery. CMS also believes this proposal would reduce expenses for Medicare, Medicaid and private health insurers by reducing costs associated with reduced pre-operative exams, laboratory testing, chest radiographs, and electrocardiograms.

Table 15, reproduced below, provides information about costs and potential annual savings associated with the change from requiring a comprehensive physical examination 30 days before surgical procedures performed in ASCs to requiring that the operating physician and ASC determine which patients need more extensive assessments. CMS estimates that the total first year costs for developing policies would be \$38 million; Assuming that the comprehensive physical examination will continue to be needed for 50 percent of all patients, CMS estimates the annual savings could be approximately \$454 million for ASCs.

Type of Cost	Unit Cost	Number (M)	Current Total Cost (M)	Twenty-Five Percent Retained (M)	Fifty Percent Retained (M)	Seventy-Five Percent Retained (M)	Eighty-Five Percent Retained (M)
Physical Examination	\$100	4.56	\$456	\$114	\$228	\$342	\$388
Test Batteries	\$100	2.28	\$228	\$57	\$114	\$171	\$194
Patient Travel Cost	\$36	4.56	\$164	\$41	\$82	\$123	\$140
Administrative Cost to ASC	\$5	4.56	\$23	\$6	\$11	\$17	\$19
Surgical Cancellations*	\$161	0.228	\$37	\$9	\$18	\$28	\$31
Total Cost, ASC			\$908	\$227	\$454	\$681	\$772
Total Cost, Hospital Outpatient**			\$908	\$227	\$454	\$681	\$772
Total Cost			\$1,815	\$454	\$908	\$1,362	\$1,544
Total Savings				\$1,362	\$908	\$454	\$272

* Based on information from a major ASC, this estimate assumes that 5 percent of scheduled cataract operations are cancelled at the last minute since the required history and physical information and test results have not arrived from the physician office doing the examination and the tests. CMS estimates assume one half hour of surgeon time wasted (\$234 an hour), one half hour of RN time wasted (\$69 an hour), and ten minutes of clerical time (\$32 an hour) to reschedule.

** Hospital outpatient savings assumed to be equal to ASC savings.

C. Hospice

1. Hospice Aide and Homemaker Services (§418.76)

The hospice CoPs require all hospice aides to meet specific federally-established, training and education requirements. Specifically, §418.76(a) requires a hospice aide must be a person who has completed one of the following: (1) a training program and competency evaluation as specified in the regulations; (2) a nurse aide training and competency evaluation program in accordance with the requirements in the long term care requirements; or (3) a state licensure program that meets the requirements of §418.76(b) (training) and (c) (competency evaluation). The specific content and format of aide education, training, and competency evaluations are detailed in §418.76(b) and (c).

CMS proposed to revise §418.76(a)(1)(iv) to remove the requirement that a state licensure program must meet the specific training and competency requirements set forth in §418.76(b) and (c) in order to be deemed an appropriate qualification for employment. This change would defer to state licensure requirements, except in states where no requirements exist.

Many commenters supported the proposed revision to defer to existing state requirements for hospice aide training. Some commenters did not support this proposal stating that state education and training standards should not be accepted as sufficient to assure patient health and safety. In response, CMS states that deference to state standards about training and competency of health care professionals is standard practice and that imposing a separate federal standard is unnecessary.

CMS finalizes its proposal. In the absence of state requirements, hospices will continue to be required to assure that an aide meets the federal training standards. CMS would still require that hospice aides may only perform those skills that are consistent with the training that the aide has received (§418.76(g)(2)(iv)) and if an area of concern is verified by the hospice during an on-site aide supervision visit, then the hospice aide must complete a competency evaluation in accordance with §418.76(c) and (h)(1)(iii).

2. Drugs and Biologicals, Medical Supplies, and Durable Medical Equipment (§418.106(a)(1) and (e)(2)(i))

The hospice CoPs require that the hospice's interdisciplinary group confer with an individual with education and training in drug management (as defined in hospice policies and procedures and state law) and is an employee of or under contract with the hospice to ensure that drugs and biologicals meet each patient's needs (§418.106(a)(1)). To fulfill this requirement, hospices can use a licensed pharmacist or an individual with extensive knowledge of drugs.

Section 418.106(a)(1). CMS proposed to delete the requirements at §418.106(a)(1). Hospices would continue to be required to comprehensively assess patients on a regular schedule and on an as-needed basis (§418.54(a), (b), and (d)), and to assure that each patient's plan of care is developed and continually updated to meet each patient's needs as identified in the assessment process (§418.56(b) through (d)).

Many commenters supported this proposal because it is standard practice in hospices. Other commenters agreed it is standard practice but thought there was value in having the regulatory requirement.

CMS finalizes the proposed change to remove the process requirement at §418.106(a)(1).

Section 418.106(e)(2). Hospices are required at §418.106(e)(2) to do the following: (1) provide a copy of the hospice written policies and procedures on the management and disposal of controlled drugs to the patient or representative and family; (2) discuss the hospice policies and procedures for managing the safe use and disposal of controlled drugs with the patient or representative and the family in a language and manner that they understand to ensure these parties are educated regarding the safe use and disposal of controlled drugs; and (3) document in the patient’s clinical record that the written policies and procedures for managing controlled drugs were provided and discussed.

CMS proposed to replace the requirement that hospices provide a physical paper copy of policies and procedures with a requirement that hospices provide information regarding the use, storage, and disposal of controlled drugs to the patient or representative and family, which can be developed in a manner that addresses the perspective and information needs of patients and families. CMS proposed to require, that regardless of the format chosen, the information must be provided in a manner that allows for continual access to the information on an as-needed basis.

Many commenters supported this proposal and the goal of improving patient and family education about controlled drugs. A few commenters were concerned this proposal conflicted with section 3222 of the Substance Use- Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (“SUPPORT Act”) (Pub. L. 115-271).¹ This provision requires hospices which permit their employees to dispose of medications in the patient’s home, to provide their written policies and procedures to patients, families and caregivers.

Because of the requirements in section 3222 of the SUPPORT Act, CMS does not finalize this proposal. In addition to meeting the statutory requirements to provide a copy of the hospice’s clinical policies and procedures, CMS encourages hospices to develop easily understood materials that explain safe storage, use, and disposal of controlled drugs to patients, their families, and caregivers.

3. Hospices That Provide Hospice Care to Residents of a Skilled Nursing Facility/Nursing Facility or Intermediate Care Facilities for Individuals with Intellectual Disabilities

(§418.112(c)(10) and §418.76(b))

Section 418.112(f) of the hospice CoPs requires hospices to assure orientation of staff furnishing hospice care to patients in a skilled nursing facility/nursing facility (SNF/NF) or Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID). This orientation is to ensure that facility staffs are provided information on the hospice’s philosophy and approach to care in the same way that home caregivers are routinely provided information about the hospice.

¹ Section 3222 of the SUPPORT Act amends section 302 of the Controlled Substances Act (21 U.S.C. §822) which is under the jurisdiction of the Department of Justice.

CMS proposed to remove §418.112(f) and move the requirement for facility staff orientation to the standard related to the written agreement established between hospices and facilities at §418.56(c)(10).

Commenters supported the intent of the proposal to reduce regulatory burden but were concerned that requiring this topic be added into a written agreement would create a onetime burden for hospices of renegotiating the written agreement with each long term care facility and this burden was not acceptable. Some commenters suggested the current regulations be revised to allow for hospices and facilities to negotiate their respective roles and responsibilities outside of the written agreement.

In response to commenters' feedback about the burden associated with this proposal, CMS does not finalize the proposal. To achieve the original goal of adding flexibility and reducing hospice costs, CMS revises §418.112(f) to clarify that a hospice must consult with and thus share responsibility with the facility to assure facility staff orientation and training.

4. Regulatory Impact Analysis

CMS estimates that the finalized hospice reforms will generate a total annual savings of approximately \$97.4 million for the 4,602 Medicare participating hospices. CMS estimates the final policy to defer to state training and competency requirements will save approximately \$2.3 million; the regulatory changes to the requirements for interdisciplinary group meetings related to drugs and biologicals would save approximately \$94.3 million; and the regulatory changes to streamline facility staff orientation will save approximately \$0.8 million.

D. Hospitals

1. Quality Assessment and Performance Improvement Program (QAPI, §482.21)

CMS proposed that the system governing body legally responsible for a hospital system consisting of two or more separately certified hospitals could elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable state and local laws. Each separately certified hospital subject to the system governing body would have to demonstrate that the unified and integrated QAPI program:

- Is established in a manner accounting for each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and
- Establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

Commenters generally supported the proposed changes with a few commenters recommending that individual, hospital-specific data be recorded and made available to the system's governing

body and the public. One commenter recommended that the governing body consult with each of its separately certified hospital's medical staff.

CMS' requirement will not prohibit an individual hospital from reporting its own data to the governing body. Each separately certified hospital in the system must demonstrate that the unified and integrated program has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed. CMS provided multiple references to provisions of the CoPs that already require accountability between the hospital's medical staff and its governing body.

The proposal is being finalized without change.

CMS estimates annual savings of about \$31 million from allowing a unified QAPI program for multi-hospital systems. The cost of compliance is estimated to be \$10,000 per year per hospital. Under the final rule, instead of all 4,823 participating hospitals complying with the requirement, only 1,330 hospitals that do not participate in a hospital system and 424 systems would be required to comply, reducing the total burden from \$48.2 million to \$17.5 million. A \$1 million cost is estimated for the associated information collection requirements.

2. Medical Staff, Medical Record Services, and Surgical Services (§§482.22, 482.24, and 482.51)

CMS proposed a new provision that would allow the medical staff the option to develop and maintain a policy that identifies specific patients that may have a simplified assessment in place of a comprehensive medical history and physical (H&P) examination, or any update to it, prior to specific outpatient surgical or procedural services. If the medical staff exercised the option to perform a simplified assessment in some cases, the policy for each procedure would need to indicate:

- The hospital's consideration of patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure;
- Nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures; and
- Applicable state and local health and safety laws.

CMS proposed the change to §482.22(c)(5) that applies to "Medical Staff" and analogous changes to §482.24, "Medical Record Services" and §482.51, "Surgical Services." These changes are consistent with those for ambulatory surgical centers discussed earlier in this summary.

The majority of comments submitted were supportive of the proposed changes as long as they are based on recognized guidelines and best practices as well as on the clinical judgment of the medical staff. Several commenters raised specific concerns about the proposal including the burden of assessing patients shifting from the patient's primary care physician or surgeon to the anesthesiologist. Some commenters asked for guidance about situations where there are no clear

and recognized guidelines for pre-surgical patient assessment for specific classes of patients undergoing certain outpatient surgeries and procedures.

In response to the specific concerns of some commenters, CMS stated the revision will be a regulatory option available to hospitals. The hospital and its medical staff may exercise flexibility provided by the regulations based on the medical staff's clinical judgment supported by nationally recognized evidence and guidelines for best practices.

With respect to anesthesia, CMS indicates that a separate CoP provision requires that a pre-anesthesia evaluation be completed within 48 hours of a procedure requiring anesthesia. The anesthesiologist is responsible for this evaluation, but not for the H&P, update, and pre-surgical assessment requirements. An anesthesiologist may qualify to do the pre-surgical assessment, but the hospital would need to demonstrate that these pre-surgical assessments are (1) separate and distinct from the pre-anesthesia evaluation; in accordance with state law; and (2) consistent with the current standards of both anesthesia care and surgical care.

If there are no clear and recognized guidelines or recommendations for pre-surgical patient assessment for specific classes of patients undergoing certain outpatient procedures, CMS advises the hospital and its medical staff to not include those classes of patients and outpatient procedures in its presurgical patient assessment policy.

CMS is finalizing the proposed rule with a correction of “oromaxillofacial surgeon” to “oral and maxillofacial surgeon.”

CMS estimates that the burden associated with updating or writing new hospital policies would result in an annual cost of \$11.9 million across all 4,823 hospitals. See page 5 of this summary for discussion of potential savings from removing the requirements for a H&P within 30 days prior to surgery. Assuming that the comprehensive physical examination will continue to be needed for 50 percent of all patients, CMS estimates the annual savings could be approximately \$454 million for outpatient hospital departments.

3. Medical Staff: Autopsies (§482.22(d))

CMS proposed to remove the requirement at §482.22(d) that a hospital's medical staff should attempt to secure autopsies in all cases of unusual deaths and of medical-legal and educational interest. If an autopsy is done, the mechanism for documenting permission must be defined and there must be a system for notifying the medical staff, specifically the attending practitioner.

Comments/Responses: There were comments both supporting and opposing the proposal. In cases of medical-legal interest, many commenters stated that hospitals should report the death to, and consult with, their local medical examiner, coroner, or medicolegal death investigative authority rather than obtaining family permission and performing an autopsy. A few commenters suggested requiring the patient (or a representative) upon admission to affirmatively allow or prohibit an autopsy in the event of death.

CMS defers to state law on autopsies in medical-legal cases in accordance with state law. Mandating that hospitals perform autopsies, or that hospitals ask permission to perform an

autopsy upon a patient's admission, would be unduly burdensome to hospitals and contrary to the purpose of the CoPs, which establish baseline health and safety requirements. However, hospitals may choose to establish their own policies on performing autopsies in circumstances not required by the CoPs.

The proposal is being finalized without change. CMS does not anticipate that hospitals will accrue savings from removal of this requirement because they must still comply with the more detailed, specific requirements regarding medical-legal autopsies that are required under state laws.

4. Infection Control (§482.42)

CMS proposed a unified and integrated program for infection control for multi-hospital systems as it did for the QAPI program. Parallel requirements as those proposed for the QAPI program were proposed for hospital infection control. The proposed rule included a specific request for public comment on whether there are any other programs currently required under the CoPs for each separately certified hospital, beyond the QAPI and infection control programs, that would be better managed under a system governing body legally responsible for the conduct of each separately certified hospital.

Commenters supported CMS' proposal. Some commenters requested CMS adopt analogous requirements for specific other services. CMS responded that their suggestions were beyond the scope of the proposed rule.

CMS is finalizing the proposed changes. In addition, CMS is finalizing changes that will address the designated and qualified individual(s) at the hospital responsible for communicating with the unified infection control program, for implementing and maintaining the policies and procedures governing infection control, and for providing infection prevention education and training to hospital staff with regard to antibiotic stewardship. The changes to regulations regarding antibiotic stewardship programs must be implemented by hospitals by March 30, 2020.

Savings from this change are estimated to total \$115 million. The cost of compliance is estimated to be \$38,000 per year per hospital. Under the final rule, instead of all 4,823 participating hospitals complying with the requirement, only 1,330 hospitals that do not participate in a hospital system and 424 systems would be required to comply, reducing the total burden from \$183 million to \$67 million; a \$1 million cost is estimated for the information collection requirements.

5. Special Requirements for Hospital Providers of Long-Term Care Services ("Swing-Beds") (§482.58(b)(1), (4), (5), and (8), and Identical CAH requirements: §485.645(d)(1), (4), (5), (6), and (7))

Under current regulations, swing beds in small rural hospitals and CAHs are subject to the same requirements that apply to long-term care facilities (SNFs and nursing homes). CMS has found that the average length of stay in a swing bed is much shorter than in a long-term care facility and is proposing changes to regulations for the following:

Voluntary Performance of Services. Long-term care facility regulations regarding voluntary performance of services for the facility apply to residents in swing beds. CMS proposed to eliminate these regulations (§§482.58(b)(1) and (c) and 485.645(d)(1)) on the basis that it is unlikely that patients receiving hospital and CAH swing-bed services would have an opportunity to provide services at the hospital or CAH due to their relatively short length of stay.

Hospital and CAH swing-bed providers offering patients the option of providing services for the facility are expected to have current policies and procedures that include protocols for establishing an agreement between the two parties.

Commenters supported the proposal that is being finalized without change.

CMS estimates total savings of \$8.2 million across all 478 swing-based hospitals from elimination of the documentation associated with this regulatory requirement (\$17,056 per provider X 478 hospital swing-bed providers).

Comprehensive Assessment and Care Plans. CMS proposed to eliminate regulations requiring a comprehensive assessment and care plan, surveys of the preferences of each resident, an ongoing program to support residents in their choice of activities and an activities program that must be directed by a qualified professional who is a qualified therapeutic recreation specialist or activities professional. CMS believes these regulations are burdensome given the relatively short stays patients have in swing beds.

For those patients who receive swing-bed services for an extended period of time, their nursing care plans – as required under §482.23(b)(4) for hospitals and §485.635(d)(4) for CAHs – are based on assessing the patient’s nursing care needs and will support care that holistically meets the needs of the patient, taking into consideration physiological and psychosocial factors.

Commenters supported CMS’ proposal, generally agreeing that the activity needs of those patients who receive swing-bed services for an extended period of time would be met via the hospital and CAH nursing care plan requirements. One commenter noted the nursing care plan will not include interest-based group and individual activities that support the patient’s physical, mental and psychosocial well-being. Therapeutic or recreational activities differ significantly from the goals that normally would be identified in a nursing care plan.

CMS responded that it expects hospitals and CAHs to use an interdisciplinary approach to providing services that meet the needs of all of their patients, including those receiving swing bed services, regardless of length of stay. If the needs of the patient include interest-based group and individual activities that support the patient’s physical, mental and psychosocial well-being, CMS expects that the hospital or CAH will provide these services to the patient. CMS is finalizing its proposal without change.

Each swing-bed hospital or CAH is estimated to save \$46,640 from elimination of this requirement, for a total of \$20.4 million across all hospital swing-bed providers.

Social Worker Requirements for Facilities with more than 120 Beds. Long-term care facilities with more than 120 beds must employ a qualified social worker on a full-time basis. These same requirements apply to swing beds even though swing beds are only permitted in rural hospitals with less than 100 beds or less and CAHs with 25 beds or less. CMS proposed to eliminate the social worker requirement at §§482.58(b)(5) and 485.645(d)(5). Commenters agreed. CMS is finalizing the provision without change. No impact is estimated from eliminating this provision, which in practice does not affect either hospital or CAH swing-bed providers.

Routine and Emergency Dental Services. CMS proposed to eliminate long-term care facility requirements for routine and emergency dental services to meet the needs of each resident for patients in swing beds (§§482.58(b)(7) and 485.645(d)(7)). CMS expects that any required dental services that necessitate immediate treatment would be considered an emergency and be addressed under provisions requiring hospitals to have written policies and procedures for appraisal of emergencies, initial treatment, and referral necessary to meet the needs of its inpatients and outpatients. Commenters agreed and CMS is finalizing the provision without change.

CMS estimates that elimination of this requirement will save about \$815,000 annually across the 478 hospital swing bed providers (\$1,704 X 478).

6. Special Requirements for Psychiatric Hospitals (§482.61(d))

Section 482.61(d) requires that progress notes be documented by the doctor of medicine (MD) or doctor of osteopathy (DO) responsible for the care of the patient and, when appropriate, “others significantly involved in active treatment modalities.” CMS believes this provision requires clarification. It proposed to revise §482.61(d) to include physician assistants, nurse practitioners, psychologists, and clinical nurse specialists, when acting in accordance with state law, their scope of practice, and hospital policy as the types of practitioners that may document progress notes.

Commenters were mostly supportive of the proposal. One commenter opposed the proposed change, noting that the existing regulatory language already permits non-physician practitioners to document progress notes in the patient’s medical records. Another commenter opposed the inclusion of psychologists in the list of non-physician practitioners allowed to document the patient’s progress notes saying that current regulations permit psychologists to document the services they provide (psychotherapy, psychological/neuropsychological testing notes), but they should not be granted new authority to write medical progress notes. One commenter requested clarification of the phrase “hospital policy” as it relates to the requirement that non-physician practitioners act in accordance with hospital policy.

CMS responded that there is a need to clarify the intent of the regulatory text as it does not specify the non-physician practitioners who can document progress reports. The majority of commenters agreed. CMS further states that a clinical psychologist has the authority to admit patients and oversee the care of Medicare patients (but only with respect to clinical psychologist services as defined in § 410.71 and only to the extent permitted by state law) implying that the clinical psychologists have authority to write medical progress notes and including them in the regulation explicitly is not granting them any additional authority they do not currently have.

“Hospital policy” means psychiatric hospitals’ compliance with the hospital CoPs that require that the hospital’s governing body approve all hospital policies. The governing body must determine (in accordance with state law) which categories of practitioners are eligible candidates for appointment to the medical staff. The governing body is required to appoint members of the medical staff after considering the recommendations of the existing members of the medical staff and approve medical staff bylaws and other medical staff rules and regulations. Non-physician practitioners, whether employees or contractors, would be subject to all rules, regulations, and policy manuals utilized by the hospital.

CMS is finalizing the proposal without change. The savings from these revisions are estimated to total \$153.5 million across 620 psychiatric hospitals.

E. Transplant Centers

CMS adopts several changes to the regulations for transplant centers set forth in §§482.68 through 482.104. The current regulations were added in 2007 in an effort to increase the quality of care by specifying minimal health and safety standards.

Specifically, the final rule modifies the nomenclature used, remove requirements for re-approval of transplant centers, and makes related changes to the survey, certification and enforcement requirements.

1. Changes in Nomenclature (§482.68 and §482.70)

CMS updates nomenclature to be consistent with the common use of terms within the community of organ transplant providers. The term ‘transplant center’ is replaced by ‘transplant program’ throughout the CoPs for hospitals; in the CoPs for transplant centers found in §482.68 and §§482.72 through 482.104; and in §488.61, which pertains to approval and re-approval of organ transplant centers. A ‘transplant program’ is therefore defined (in §482.70) as an organ-specific transplant program within a transplant hospital (one that furnishes organ transplants and other medical and surgical specialty services required for the care of transplant patients), and it is the transplant program that will be surveyed for compliance with the CoPs.

In other nomenclature changes in these regulations, CMS will refer to “recipients” instead of “beneficiaries,” and will consistently use the term Independent Living Donor Advocate (ILDA) throughout. (This is in lieu of a “living donor advocate” or “living donor advocate team” in some places.)

2. Data Submission, Clinical Experience, and Outcome Requirements for Re-Approval of Transplant Centers (§482.82)

CMS finalizes its proposal to remove entirely the requirement that when applying for re-approval, transplant centers must meet certain data submission, clinical experience and outcome requirements. The removed requirements include submission of data by the center on all transplants performed during the prior three years. With the removal of these requirements, conforming changes are made to the regulations at §482.102(a)(5) and §488.61.

In finalizing the proposal, CMS responds to the objections of some commenters who were concerned that removal would affect quality of care and patient outcomes. In particular, commenters expressed concern about public availability of information on transplant outcomes and whether CMS would be able to identify underperforming programs. CMS replies that transplant outcomes will still be available to the public every six months on the Scientific Registry for Transplant Recipients' website at <https://www.srtr.org/>. It intends to continue to monitor performance of approved transplant programs through the transplant and hospital QAPI programs and through the other transplant program CoPs. CMS believes that transplant programs will continue to use QAPI programs to monitor quality of care, evaluate transplantation activities and outcomes, and conduct performance improvements when necessary. It views these efforts and the survey of the CoPs as providing sufficient oversight to ensure that transplant programs will maintain high standards of care. Regarding surveys, CMS notes that the state survey interval will not change and that public or confidential reports may trigger a complaint survey.

Further, CMS notes studies and professional opinions submitted by commenters regarding the unintended consequences of the re-approval requirements that bolster the concerns that led it to propose their removal. It believes that removal of the re-approval requirements will lead to improved transplant outcomes, increased opportunities for patients on waitlists, improve organ procurement and organ use, and reduce administrative burdens on transplant centers. In the proposed rule, CMS had cited studies and stakeholder feedback indicating that fear of non-compliance with the outcome requirements may have had unintended consequences that reduce transplant rates among higher-risk candidates, and increase organ discards.

3. Survey, Certification and Enforcement Procedures for Transplant Centers

Complementary to the removal of the requirements for transplant center program reapproval in §482.82 as described above, CMS also amends the regulations in §488.61(f) through (h) to remove references to mitigating factors and transplant systems improvement agreements for the re-approval process. The opportunity to submit mitigating factors or engage in improvement agreements will still be part of the initial application process for Medicare approval of transplant programs.

4. Impact Analysis

With respect to collection of information requirements, CMS estimates that the proposal to remove the requirement for mitigating factors and improvement agreements with respect to re-approval of transplant programs would affect an average of 14 programs annually with savings of \$2,249 per program or \$31,486 across all programs. Removal of the reapproval application requirements is estimated to have no effect on collection of information burden because transplant programs must submit the same information to the Organ Procurement and Transplantation Network.

With respect to the overall impact of the regulatory proposals for transplant programs on the 750 Medicare-approved programs, CMS does not quantify the estimated effects but repeats from the proposed rule a lengthy qualitative discussion of the literature on how the changes now finalized might improve the number of kidney and other organ transplants by increasing the availability of organs to higher-risk patients. It concludes that the potential benefits are very substantial in light of the literature on increased life expectancy associated with transplantation, particularly for

kidneys. CMS does not expect the changes proposed in this rule to improve graft and patient survival rates.

F. Home Health Agencies

CMS adopts proposals it made to remove or modify certain regulations that were adopted in the January 2017 HHA CoP final rule (82 FR 4504), involving verbal notice of patients' rights, and home health aide competency evaluations. It does not finalize proposed changes regarding the availability of clinical records.

1. Patient Rights (§484.50(a)(3) and (c)(7))

The requirement in §484.50(a)(3), as first implemented in January 2018, that HHAs provide verbal notice of all patient rights is removed; the requirement for oral notice is limited to cases in which it is required by law. As a result, the requirement at §484.50(c)(7) is modified to require written and verbal notification of HHA payment and patient financial liability information. The requirement that notice of patient rights be provided in writing is retained along with the requirement that information be made accessible in plain language and in a manner that is accessible and timely to persons with disabilities and those with limited English proficiency. CMS reports that a small number of commenters objected to the change, pointing out that oral notice has value to patients and caregivers and is particularly important to individuals with lower literacy levels due to disabilities. In response, CMS reminds all HHAs that they must comply with provisions of the Americans with Disabilities Act and section 504 of the Rehabilitation Act when communicating with patients, including on the notice of patient rights. This includes providing equal access to individuals with disabilities including provision of auxiliary aids and alternate formats, including qualified interpreters, large print documents, Braille, digital documents, and audio recordings.

2. Home Health Aide Services (§484.80(h)(3))

Under the January 2017 HHA CoP final rule, if a supervisory on-site visit identifies a deficiency in a home health aide's skills, the HHA must conduct, and the aide must complete, a full competency evaluation to assess all the aide's skills. CMS has reassessed and concluded that this requirement is overly burdensome.

Under the final rule, the requirement for a full competency evaluation is replaced with a requirement that the HHA retrain the aide to address the deficient skills and require a competency evaluation only for those skills. CMS reports that comments overwhelmingly supported this change.

In addition, section I.M of this summary below discusses further changes involving home health aide competency evaluations that were not included in the proposed rule and are finalized in this rule on an interim basis. As discussed below, the changes codify longstanding policy to permit evaluation by observation of an aide's performance with a patient *or with a pseudo-patient or as part of a simulation* and adds definitions for these terms.

3. Clinical Records (§484.110(e))

CMS does not finalize its proposal to replace the requirement that an HHA must make a copy of the patient's clinical record available at the next home visit or within 4 days, whichever comes first, with a requirement that the record be provided within 4 days.

While comments were universally supportive, some suggestions for further revisions to the HHA clinical records requirements were offered. CMS notes the Administration seeks to address the need for electronic exchange of health information, and decides in this final rule to consider the comments it received in the broader context of interoperability and health information exchange, and will use them to inform future rulemaking.

4. Other Comments

In the final rule CMS responds to comments it received that were not directly related to the proposed rule changes. These responses emphasize the need for patients to have required information from HHAs in order to be active participants in their own care; state that a possible change to permit a registered nurse or therapist to perform the required comprehensive assessment will be considered for future rulemaking; point out that the statute requires that the plan of care be under the direction of a physician; note that verbal orders are allowed to facilitate timely care so it is not necessary for an HHA to withhold therapy services while waiting for a physician to confirm the therapy plan; and agree that communicating with all involved physicians is not necessary for every change in the plan of care.

5. Impact Analysis

CMS estimates that limiting the verbal notification requirement to only certain information as required by statute will reduce the burden on the 12,624 HHAs and result in annual savings of \$57 million. No savings are estimated for the other changes.

G. Comprehensive Outpatient Rehabilitation Facilities – Utilization Review

CMS reduces the frequency of utilization reviews that must be conducted by CORFs from quarterly to annually (§485.66). It believes that quarterly review is overly burdensome and diverts staff from patient care. A CORF is not precluded from conducting more frequent reviews. Commenters strongly supported this change. The associated savings are estimated to be \$1,680 per facility or \$315,840 across the 188 CORFs.

H. Critical Access Hospitals

Three proposals are finalized with respect to CAHs involving organizational structure, review of policies and procedures, and swing beds.

1. Organizational Structure (§485.627(b)(1))

The requirement in this section that CAHs disclose ownership and control interests in accordance with 42 CFR Part 420 Subpart C is removed because it duplicates requirements for CAHs under the provider agreement which also references the requirements in Part 420 (§489.12(a)(2)). Under the provider agreement requirements, ownership and control must be disclosed during the

provider enrollment process and updates provided to CMS. Commenters were universally supportive of the proposed change.

2. Review of Policies and Procedures (§485.635(a)(4))

The requirement for a CAH to review certain policies and procedures at least annually is changed to provide for at least a biennial review. This change is made in response to comments that the annual schedule can be burdensome and ineffective, as some reviews can take as long as a month. The policies that must be reviewed include (i) a description of the services the CAH furnishes; (ii) policies and procedures for emergency medical services; (iii) guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH ; (iv) rules for the storage, handling, dispensation, and administration of drugs and biologicals; (v) procedures for reporting adverse drug reactions and errors in the administration of drugs; (vi) a system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel; and (vii) procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices.

3. Swing Beds (§485.645(d))

Complementing the proposed changes to hospital swing-bed services described in section D.5 above, CMS similarly modifies requirements for CAH swing-bed providers. Swing-bed services are transitional SNF-level services provided on a temporary basis; CAHs may not have more than 25 inpatient/swing beds. As noted earlier, these changes are made because CMS has determined that some of the cross-referenced long-term care requirements for hospitals and CAH swing-bed providers are unnecessary and unduly burdensome given their focus on residents with longer length of stays. In addition, long-term care facilities may have more beds than those permitted for a CAH.

Specifically, CMS removes the following requirements on CAH swing-bed providers:

- The requirement to offer residents the right to choose to or to refuse to perform services for the facility and prohibition on a facility from requiring a resident to perform services for the facility. (Currently incorporated in the regulations as a cross reference to §483.10(f)(9)).
- The requirement to provide an ongoing activity program directed by a qualified therapeutic recreation specialist or activities professional. (Currently incorporated in the regulations as a cross reference to §483.24(c)).
- The requirement that providers with more than 120 beds employ a full-time qualified social worker. (Currently incorporated in the regulations as a cross reference to §483.70(p)).
- The requirement to assist in obtaining routine and 24-hour emergency dental care for residents. (Currently incorporated in the regulations as a cross reference to §483.55(a)(1)).

4. Impact Analysis

The regulatory changes finalized for the 1,343 CAHs are estimated to save \$78 million annually. The vast majority of these estimated savings (\$76.5 million) come from the changes to the

requirements affecting the 1,246 CAH swing-bed providers, with the ownership disclosure (\$143,701) and biennial policy review (\$1.3 million annualized) saving much less. The estimated savings from the swing-bed provisions break down as follows: \$21.3 million for elimination of the requirements regarding residents performing services for the facility; \$53.1 million for elimination of the requirement to provide an ongoing activity program and \$2.1 million for elimination of the requirement regarding emergency dental care. No savings are associated with eliminating the requirement for employment of a social worker since in practice this does not apply to CAHs.

I. Community Mental Health Centers (CMHCs) (§485.914(d))

1. Updating Client Comprehensive Assessments

Medicare-certified CMHCs are subject to conditions of participation that are intended to ensure the quality and safety of the entities. One of those conditions, at §485.914(d), requires a CMHC to update a client comprehensive assessment for each client every 30 days. CMS explains that for clients receiving partial hospitalization services, updating a treatment plan every 30 days is necessary based on those clients' level of acuity and changing needs as they progress through treatment. This schedule is also consistent with requirements under CMS' partial hospitalization payment regulations.

For patients of CMHCs who are not partial hospitalization program (PHP) clients, however, CMS believes that requirements to update treatment plans every 30 days is overly burdensome, does not support the needs of those clients, and is not an efficient use of CMHC clinician or client time. CMS received feedback that in many cases updates every 30 days are not being completed. As a result, CMS finalizes its proposal to modify the requirements to update each non-PHP client's comprehensive assessment "in accordance with current standards of practice" while retaining the existing requirement for PHP clients' assessments to be updated no less frequently than 30 days. CMS views the finalized change as requiring updates for non-PHP clients when there are changes in the client's status, in response to treatment, and when goals have been achieved.

CMS received four comments on this proposal, mostly supportive of this change. In response to concerns about how this assessment change would impact CMHC patients who must be transferred to a hospital emergency room, CMS notes that their transfer note typically includes a description of the client's behavior, interventions and medications provided, a description of the client's condition or symptoms, the client's response to the intervention, and all current medications and any PRN medications that were given prior to the transfer. CMS also agrees with a commenter's suggestion that conforming changes should be made to §485.916 (the client centered active treatment plan CoP). As CMS did not propose any changes to that section, it declines to do so at this time but will consider proposing a change to those requirements at a future date.

2. Regulatory Impact Analysis

CMS estimates that requiring comprehensive assessments to be updated in accordance with current standards of practice for non-PHP clients and no less frequently than 30 days for PHP clients would reduce the number of assessments needed for non-PHP clients from 12 per year to

about 2 per year. In total, there would be 20,930 fewer assessments per year among all CMHCs which would result in a total cost savings to CMHC providers of \$156,975.

J. Portable X-Ray Services

CMS proposed changes to two conditions for coverage for portable x-ray services. The first is related to the qualifications of personnel providing those services and the second to requirements for referrals for portable x-ray services.

1. Qualifications of Personnel (§486.104(a))

Existing §486.104(a) describes the training and education requirements of a portable x-ray technologist with a focus on the accreditation of their school or training program. CMS finalizes without change its proposal to better align this section with the requirements elsewhere in Medicare regulations for technical personnel providing x-ray services.

CMS explains that in other sections of existing rules that govern the same type of technologists, there are not have parallel accreditation requirements for education and training programs. For example, §482.26(c)(2) simply requires a hospital to only allow personnel designated as qualified by the medical staff to use radiologic equipment. Existing §410.33(c) which describes the necessary qualifications for non-physician personnel of an independent testing facility requires them to demonstrate the basic qualifications to perform the tests and have training and proficiency as evidenced by licensure or certification by the appropriate state health or education department or to be certified by an appropriate national credentialing body.

CMS finalizes without change its proposal to replace the four training and education requirements in §482.104(a)² with the requirement that all operators of portable x-ray equipment must have successfully completed (i) appropriate and formal training in x-ray technology and demonstrated competence in the use of equipment and administration of portable x-ray procedures OR (ii) 24 full months of training and experience under the direct supervision of a physician certified in radiology or who possesses other equivalent qualifications. Commenters were supportive.

CMS notes that state licensure and personnel requirements of portable x-ray suppliers that are more stringent than the changed federal standards would not be precluded.

2. Referrals for Portable X-Ray Services (§486.106(a)(2))

Under prior rules, an order for portable x-ray services is required to be written and signed. These requirements conflict with other applicable requirements of orders for the same services under §410.32 – which specify the conditions for coverage for diagnostic x-rays, lab tests, and other diagnostic tests under Medicare Part B. In addition, CMS pointed out that they preclude

² Those requirements were: 1) Successful completion of formal training in a school approved by the Joint Review Committee on Education in Radiologic Technology or earned a BA or Associates Degree in radiologic technology from an accredited college or university; 2) For those whose training was completed between 1960 and 1966, completion of training under the direct supervision of a physician and experience; 3) For those whose training was completed before 1960, similar to those in number 2); or 4) For those whose training was completed before 1993, completion of a program of formal training in x-ray technology in a school approved by the Council on Education of the American Medical Association, or by the American Osteopathic Association.

telephone and electronic orders, and have the effect of sometimes requiring providers to write two sets of orders for the same procedure – one that complies with §486.106(a)(2) and a second that complies with §410.32.

CMS finalizes its proposal, without change, to update §486.106 by cross-referencing the existing requirements for ordering x-ray services under §410.32. CMS retains the existing requirement that portable x-ray orders must include a statement describing why it is necessary to use a portable x-ray instead of providing the service in a facility. Commenters generally were supportive.

3. Regulatory Impact Analysis

CMS estimates that the changes to the training and education requirements under §482.104(a) present a savings opportunity of approximately \$31 million in the first year primarily attributable to the ability of providers under the proposed changes to hire lower-cost x-ray technologists who may not have advanced certification.

The proposed changes to §486.106(a)(2) would eliminate the burden associated with writing orders for referrals for portable x-ray services. CMS estimates that about 4 million written orders would be eliminated, reducing the staff time required for referring a patient for portable x-ray services. It would also eliminate the cost of printing and faxing those orders to physician offices. These savings would total just over \$14 million. In addition, CMS estimates 2 million follow-up calls seeking the status of such orders would be eliminated, with an associated savings of \$11 million, and reducing printing and faxing of verbal orders would save \$2.5 million. Altogether the finalized provisions are estimated to save \$27.7 million.

K. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Annual Review of Patient Care Policies (§491.9(b)(4))

CMS finalizes without change its proposal to reduce the frequency of this review from being required annually to every two years. Under prior rules in §491.9(b)(4), RHCs and FQHCs are required to have their patient care policies reviewed annually by a designated group of professionals who advise in developing such policies. Commenters supported the goal of this change, although a few questioned the extent of actual burden reduction. A recommendation for further burden reduction by removing the requirement for the group of reviewing professionals to include an individual from outside of the clinic's or center's staff was deferred to future rulemaking.

2. Program Evaluation (§491.11(a))

CMS finalizes without change its proposal to reduce the frequency of RHC and FQHC program reviews from being required annually to every two years. Under prior rules in §491.11(a), RHCs and FQHCs were required to undertake an annual evaluation of their "total program." The evaluation must include review of use of services, a sample of patient clinical records, and the clinic's or center's policies. After such a review, the staff must consider the findings of the evaluation and take corrective action if necessary. CMS points out that an RHC or FQHC could choose to conduct this evaluation more frequently it wishes – or to focus more frequent reviews on more limited program areas. Commenters expressed appreciation for the added flexibility.

3. Regulatory Impact Analysis

CMS estimates that the number of reviews of patient care policies will be halved among the 12,034 RHC and FQHC delivery sites. Each of those reviews is estimated to take 4 hours and cost each facility \$608. Altogether, the savings would total \$7.3 million and eliminate 48,136 hours spent on these activities.

CMS estimates that the number of program evaluations will also be halved among the 12,034 RHC and FQHC delivery sites. Each of those reviews is estimated to take 6 hours and cost each facility \$822. Altogether, the savings would total \$9.9 million and eliminate 72,204 hours spent on these activities.

L. Emergency Preparedness

In September 2016, CMS issued a rule establishing emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers.³ The rule requires a facility to have an emergency preparedness program that includes risk assessment and emergency planning, policies and procedures, a communication plan, training and testing. CMS finalizes several changes to these rules to reduce provider and supplier burden without, according to CMS, undermining emergency preparedness. Modifications include changes to the schedule for reviewing, training, and testing Emergency Preparedness programs and communications plans, to certain documentation requirements, and to testing requirements.

CMS received 300 comments on these proposed changes. In response to some of those comments, CMS declines to adopt a delay in the implementation of these changes, notes that it will continue to look for ways to improve quality and safety oversight including reviewing recommendations in the report “Sheltering in Danger,”⁴ and will consider additional relief for outpatient providers in future rulemaking.

Except where specifically indicated below, facilities impacted by these changes include hospitals, RNHCIs, ASCs, Hospices, PRTFs, PACE organizations, LTCFs, ICF/IIDs, HHAs, CORFs, CAHs, Organizations (which include clinics, rehabilitation agencies, public health agency providers of outpatient physical therapy, and speech-language pathology services), CMHCs, OPOs, RHCs/FQHCs and ESRD facilities.

1. Schedules for Reviewing Emergency Preparedness and Communications Plans and Training Programs

Under prior rules, facilities are required to review emergency preparedness plans including their emergency preparedness communication plans annually. In addition, they were required to develop and maintain a training program which must be provided at least annually.

³ Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (81 FR 63860).

⁴ This report, written by the Minority Staff of the Senate Finance Committee, is available at [https://www.finance.senate.gov/imo/media/doc/Sheltering%20in%20Danger%20Report%20\(2%20Nov%202018\).pdf](https://www.finance.senate.gov/imo/media/doc/Sheltering%20in%20Danger%20Report%20(2%20Nov%202018).pdf)

CMS proposed to change the schedule for reviews of emergency preparedness and communications plans to at least every 2 years for all affected providers. Commenters mostly were supportive of this change, except related to LTC facilities. CMS finalizes the change for all but LTC facility providers. For those providers the existing annual review would continue to apply. It notes that this is due to the vulnerability of residents of LTC facilities. CMS reiterates its expectation (previously included in the preamble of the 2016 final rule) that if a facility experiences an emergency, then it must analyze its response and make any necessary improvements or revisions to its emergency plan to improve its response to similar challenges.

CMS also proposed to alter the existing annual requirement for emergency preparedness training. Under the proposed rule, facilities would have been required to provide emergency preparedness training biennially following initial training on their emergency program. Additional training was required if an emergency plan were significantly updated. CMS finalizes those changes with one major exception. In response to comments in which nursing home resident advocates overwhelmingly opposed the changes, CMS does not adopt them for LTC facilities. Instead, LTC facilities will retain the existing requirement for annual training on their emergency program. All other providers will be required to conduct biennial training.

2. Documentation of Cooperation Efforts

CMS finalizes without change its proposal to eliminate requirements that facilities document their efforts to contact local, tribal, regional, state, and federal emergency preparedness officials and facilities' participation in collaborative and cooperative planning efforts. Many commenters were supportive, but a few were concerned about loss of transparency of cooperative efforts. CMS notes that facilities will continue to be required to include a process for cooperating and collaborating with those officials in their plans.

3. Annual Emergency Preparedness Testing

Under existing rules, providers are required to test their emergency plan at least annually. Two test exercises must be conducted each year; a full-scale exercise requiring activation of the plan, and an additional exercise that is either a second full-scale exercise or a tabletop exercise including group discussion and a facilitator. There is an exemption from the requirement to conduct a full-scale exercise in the year following an actual event.

In the preamble of the proposed rule, CMS clarified the types of exercises that may be conducted to meet the testing requirements; proposed additional options for certain inpatient providers to meet those requirements; and for outpatient providers, proposed to require only a single testing exercise be conducted each year instead of both a full-scale and a functional exercise. CMS also clarified the full-scale testing requirement exemption for facilities that have experienced an actual event.

CMS further provided additional clarification of its expectations for a "full-scale exercise" and what it described as a functional exercise including a tabletop exercise. A full-scale exercise is a multi-agency, multijurisdictional, multi-discipline exercise involving "boots on the ground." CMS expects that such exercises include coordination across the public health system and local geographic area if possible. A functional exercise is one that examines or validates the

coordination command and control between various multi-agency coordination centers. It does not necessitate boots on the ground.

CMS finalizes its proposals without substantive change – only making minor wording changes to improve clarity. As a result, its proposal to change the testing requirements for most *inpatient* providers to increase their flexibility is finalized. Under the final rule, one of the two annually required testing exercises may be an exercise of the provider’s choice which could include a full-scale exercise, a functional exercise, a drill or a tabletop exercise. Inpatient providers subject to this change include inpatient hospice facilities, PRTFs, hospitals, LTCFs, ICFs/IIDs, and CAHs. Most commenters supported the proposed differentiation of requirements for inpatient providers from those for outpatients.

CMS also finalizes its proposal to allow most outpatient providers and RNHCIs to only be required to provide a single testing exercise per year and a second exercise at least every two years. The first must be a full-scale exercise. The second may be a full-scale exercise, a mock disaster drill, or a tabletop exercise or workshop led by a facilitator. Providers subject to this change would be ASCs, freestanding/home-based hospice providers, PACE organizations, HHAs, CORFs, Organizations, CMHCs, RHCs, FQHCs, and ESRD facilities. OPOs will have the option of providing either a tabletop exercise or workshop each year.

CMS finalizes clarifications to the application of the testing exemption for facilities that have experienced an actual event. If a facility experiences an actual natural or man-made emergency that requires activation of their emergency plan, then they would be exempt from their next required full-scale exercise for one year following the onset of the event.

4. Regulatory Impact Analysis

CMS estimates the reduction in burden for the finalized changes to emergency preparedness requirements to be a combined savings across all facilities of \$112 million. The table below incorporates information from Tables 9, 10, 11 and 12 of the final rule.

**Estimated Cost Savings for Proposed Changes to Emergency Preparedness Provisions
(in thousands of dollars)**

Provider/ Supplier	Proposed Change			
	Biennial Review of Plans	Documentation of Collaboration	Training Programs	Testing
RNHCIs	\$ 9.7	\$ 2	\$ 4	--
ASCs	\$ 6,257	\$ 532	\$ 1,289	\$1,091
Hospices	\$ 5,916	\$ 480	\$ 956	\$ 574 (freestanding/home-based)
PRTFs	\$ 570	\$ 40	\$ 132	--
PACE	\$ 232	\$ 25	\$ 99	\$ 41
Hospitals	\$ 11,700	\$ 159	\$ 2,066	--
LTCFs	---	\$ 1,675	--	--

Provider/ Supplier	Proposed Change			
	Biennial Review of Plans	Documentation of Collaboration	Training Programs	Testing
ICFs/IIDs	\$ 3,475	\$ 652	\$ 1,735	--
HHAs	\$ 16,512	\$ 1,351	\$ 8,066	\$ 4,040
CORFs	\$ 144	\$ 20	\$ 74	\$ 56
CAHs	\$ 1,693	\$ 107	\$ 997	--
Organizations	\$ 1,241	\$ 222	\$ 843	\$ 310
CMHCs	\$ 150	\$ 17	\$ 57	\$ 23
OPOs	\$ 121	\$ 6	\$ 113	\$ 13
RHCs/FQHCs	\$ 10,108	\$ 1,288	\$ 6,246	\$ 3,147
ESRD Facilities	\$ 11,505	\$ 738	\$ 2,914	--
Total impact of provision	\$ 69,639	\$ 7,316	\$ 25,593	\$ 9,296

M. Technical Corrections and Waiver of Proposed Rulemaking

In response to comments it received regarding home health aide competency evaluations, CMS finalizes on an interim basis changes that were not included in the proposed rule. Specifically, the HHA aide competency evaluation requirement at §484.80(c)(1) is modified to permit evaluation by observation of an aide’s performance with a patient *or with a pseudo-patient or as part of a simulation*. In addition, in §484.2 definitions are added for the terms “pseudo-patient” and “simulation” as follows:

- Pseudo patient means a person trained to participate in a role-play situation, or a computer-based mannequin device. A pseudo-patient must be capable of responding to and interacting with the home health aide trainee, and must demonstrate the general characteristic to the primary patient population served by the HHA in key areas such as age, frailty, functional status, and cognitive status.
- Simulation means a training and assessment technique that mimics the reality of the homecare environment, including environmental distractions and constraints that evoke or replicate substantial aspects of the real world in a fully interactive fashion, in order to teach and assess proficiency in performing skills, and to promote decision making and critical thinking.

Because it says these changes codify longstanding policy, CMS believes that notice and comment rulemaking is not needed. The policy permitting use of pseudo patients and laboratory environments for purposes of home health aide competency evaluations dates back to a July 18, 1991 HHA CoP rule (56 FR 32967). CMS is therefore using its authority to waive notice of proposed rulemaking and to issue these provisions on an interim basis. **CMS says in this section of the preamble that a 60-day public comment period for these changes is provided, but the front matter does not identify the rule as interim and no further discussion of the comment period appears anywhere in the rule.**⁵

⁵ HPA was unsuccessful in obtaining an explanation from CMS staff at the time this summary was prepared.

N. Overall Regulatory Impact

The combined net savings from all the provisions in the final rule on regulatory burden reduction are estimated to total \$843 million in the first year, and slightly more in later years. Savings would accrue primarily to providers, with savings flowing also to other payers and patients. Estimated impact of individual provisions are discussed in the sections above.

II. Final Rule: Fire Safety Requirements for Certain Dialysis Facilities

CMS finalizes provisions addressed in a proposed rule published on November 4, 2016 (81 FR 76899) relating to fire safety requirements for certain dialysis facilities as established under the Life Safety Code (LSC) published by the National Fire Protection Association (NFPA). Specifically, under the final rule requirements at §494.60(d) are updated to provide for the following:

- Dialysis facilities that do not provide one or more exits to the outside at grade level from the patient treatment area level (e.g., those located in the upper floors of a mid-rise or high-rise building) must comply with the 2012 editions of the NFPA Life Safety Code (NFPA 101) and the Health Care Facilities Code (NFPA 99) and subsequent amendments as incorporated by reference in regulatory text. This is required regardless of the number of patients served. Current regulations require these facilities to comply with the 2000 edition of the LSC.
- No dialysis facility may operate in a building that is adjacent to an industrial high hazard area, as described in NFPA 99 and its amendments. “Adjacent to” is defined as sharing a wall, ceiling or floor with a facility.
- Consistent with current regulations, specific provisions of the LSC may be waived in consideration of a recommendation by the state survey agency or at the discretion of the Secretary, if their application would result in unreasonable hardship upon an ESRD facility, but only if the waiver will not adversely affect the health and safety of the patients.

CMS is not extending the requirements to other dialysis facilities (i.e., those with grade level exits) because it believes that patients are generally capable of unhooking themselves from dialysis machines and self-evacuating in the event of an emergency and that state and local requirements are sufficient to protect patients in those facilities.

After review of the 2015 and 2018 editions of the NFPA 101 and NFPA 99, CMS does not believe that there are provisions that need to be addressed at this time. Further, it emphasizes that the LSC is not an accessibility code and that compliance with the LSC does not ensure compliance with the requirements of the Americans with Disabilities Act.

Under current policy, dialysis facilities subject to the LSC provisions must meet the requirements of the Ambulatory Health Care Occupancy Chapters 20 and 21 of the LSC. (Facilities not subject to LSC regulations must continue to meet state and local fire codes.) The final rule discusses these requirements which address doors; alcohol-based hand rubs; and extinguishment requirements. In addition, the elements of NFPA 99 are discussed, addressing the requirements to different risk categories of facilities; gas and vacuum systems; electrical systems; heating,

ventilation, and air conditioning (HVAC) systems; electrical equipment; gas equipment; hyperbaric facilities; and features of fire protection.

The finalized requirements are effective November 29, 2019.

Impact Analysis

CMS does not know how many, if any, dialysis facilities will be impacted by adoption of the 2012 editions of the NFPA 101 and NFPA 99. All states have adopted the 2012 editions so as a practical matter, all dialysis facilities are already subject to these requirements. Therefore, no impact is anticipated.

III. Final Rule: Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

A. Background

On June 16, 2016, CMS published a proposed rule in the *Federal Register*, “Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care” (81 FR 39447) to revise certain hospital and CAH requirements, including those focused on infection control, antibiotic use, and antidiscrimination. Specifically, CMS proposed to revise the conditions of participation (CoPs) for hospitals and CAHs to conform the requirements to current standards of practice and support improvements in quality of care, reduce barriers to care, and reduce some issues that may exacerbate concerns about workforce shortages. Other proposed changes were intended to clarify the application of the existing regulations or address technical issues.⁶

The proposed revisions are in 42 CFR Parts 482 and 485.

CMS states that it is now finalizing several of the proposed changes in order to modernize the hospital and critical access hospital (CAH) requirements, improve quality of care, and support HHS and CMS priorities. These changes are discussed in the following sections.

B. Provisions of the Proposed Regulations and Responses to Public Comments for Hospitals (42 CFR 482)

1. General Comments

CMS received 200 public comments on its proposed rule. Generally, most commenters expressed support for the regulatory changes. Several commenters expressed concern that CMS underestimated the time and effort required for compliance with the antibiotic stewardship and

⁶ CMS notes that a continuation notice for “Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care (CMS-3295-P) was published on June 11, 2019, (84 FR 27069). Thus, CMS states that the final rule is in accordance with the Congress' intent to ensure timely publication of final regulations – the 3-year time limit imposed by the section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA).

the hospital Quality Assessment and Performance Improvement (QAPI) requirements, especially for smaller hospitals, including CAHs.

Specific comments and responses are discussed in more detail below.

2. Implementation Timeframe

In response to comments that the proposed hospital and CAH infection control and antibiotic stewardship and QAPI provisions require additional time to implement, CMS finalizes the following implementation schedule for the provisions of this final rule:

- CAH QAPI requirements - 18 months after the effective date of this final rule, March 30, 2021;
- Hospital and CAH compliance with the antibiotic stewardship requirements – six months from the effective date of this final rule, March 30, 2020; and
- All other requirements, including those for patient’s rights - 60 days from the publication of this final rule, November 29, 2019.

3. Non-Discrimination

CMS did not finalize its proposal to establish at §482.13(i) for hospitals and §485.635(g) for CAHs, explicit requirements that a hospital not discriminate on the basis of race, color, national origin, sex (including gender identity), age, or disability and that the hospital establish a written policy prohibiting discrimination on all of these bases. The hospital (or CAH) would also have to inform each patient (and/or support person, where appropriate), in a language he or she can understand, of his or her right to be free from discrimination against them. Part of the required information would instruct the individual on how to file a complaint if they encounter discrimination.

Commenters expressed concern about the potential technical difficulties that may exist when implementing this proposal and that the proposed requirement may be duplicative of other current federal requirements. In response, CMS is not finalizing this proposal §482.13(i) for hospitals and §485.635(g) for CAHs to require explicit non-discrimination requirements in the CoPs and instead states that it defers to the non-discrimination requirements of Section 1557 of the Affordable Care Act (ACA).

4. Licensed Independent Practitioner

Under current §482.13(e)(5), the use of restraint or seclusion must be in accordance with the order of a physician or other *licensed independent practitioner* who is responsible for the care of the patient as specified under §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with state law.

CMS finalizes its proposal to delete “independent” from “licensed independent practitioner” in order to address concerns, including from the American Academy of Physician Assistants (AAPA), that this term is not used in the Act or other federal law and that its use not only leads to confusion but also restricts the ability of hospitals to utilize physician assistants (PAs) to the

extent of their educational preparation and scope of practice, as determined by state law. CMS reviews its considerations of this issue (see 81 *FR* 39451). It concludes that the deletion of “independent” from the patient rights section of the CoP is merited in subparagraph (e)(5) and also at (e)(8)(ii). The latter relates to the situation when a new order for the use of restraint or seclusion is written for the management of violent or self-destructive behavior. A physician or other licensed independent practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with state law must see and assess the patient. Additional sections in the regulations where this change would be made are at: §482.13(e)(10), (e)(11), (e)(12)(i)(A), (e)(14), and (g)(4)(ii).

CMS also finalizes its proposal to remove the term “physician assistant” from the current provisions at §482.13(e)(12)(i)(B) and (e)(14). It explained that its use in these instances distinguishes the role of PAs from other licensed practitioners (such as advanced practice registered nurses (APRNs)) in ways that are confusing and that restrict the ability of hospitals to utilize PAs to the extent of their educational preparation and scope of practice. CMS says that this can create a burden for hospitals, particularly small hospitals, and is contrary to state laws that allow PAs to practice to the full extent of their training and credentialing. Also, CMS attests that PA training and education is comparable in many ways to that of APRNs and, in some ways, more extensive. CMS does not believe that PAs should have to undergo additional training so that they can order restraint and seclusion.

The majority of commenters were supportive of these changes, and noted that proposed language will remove uncertainty regarding these provisions and clearly demonstrate that PAs are authorized to order restraint and seclusion, in accordance with state law and facility policy, and when medical necessary to protect patients and health professionals.

5. Quality Assessment and Performance Improvement (QAPI) Program (§482.21)

CMS finalizes its proposed revision to §482.21(b) to require that the hospital QAPI program would have to incorporate quality indicator data including patient care data (submitted to or received from quality reporting and quality performance programs) including, but not limited to data related to hospital readmissions and hospital-acquired conditions. CMS notes that most hospitals collect and analyze data for several quality reporting and quality performance programs, and it would therefore be efficient and cost-effective for a hospital to include at least some of these data in its QAPI program.

CMS mostly received positive feedback, but some commenters asked that it remove the provided example of “data related to hospital readmissions and hospital-acquired conditions”, as it makes it unclear to hospitals that they should utilize all data available to them. CMS disagrees with this comment and believe that the intent of the regulation is clear that the data to be incorporated is not limited to data related to hospital readmissions and hospital-acquired conditions. CMS also says that it will ensure that the intent is clear in the interpretive requirements for this guideline.

6. Nursing Services (§482.23)

Under the current CoP for nursing services, paragraph (b) requires nursing services to have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed. There must be supervisory and staff

personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for bedside care of any patient. CMS believed that these requirements may be ambiguous and confusing due to unnecessary distinctions between inpatient and outpatient services, or may fail to account for the different ways in which a hospital may meet its nurse staffing requirements.

CMS finalizes its proposal to revise paragraph (b) to delete the term “bedside” so that readers do not believe the requirement refers only to inpatient services. The revised regulatory text reads: “There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for care of any patient.”

CMS finalizes its proposal in new (b)(7), with modifications, to allow a hospital to establish a policy specifying which, if any, outpatient departments would not be required to have an RN physically present as well as the alternative staffing plans that would be established under such policy. CMS would require such a policy to take into account factors such as the services delivered, the acuity of patients typically served by the facility, and the established standards of practice for such services. In response to a comment that approval of any nursing service policy should fall under the authority of the hospital’s nursing leadership, rather than “medical staff”, CMS replaced “medical staff” with “director of nursing” in 482.23(b)(7)(iii). This provision now states that the policy would have to be approved by the director of nursing and be reviewed at least once every three years.

CMS finalizes its proposal in §482.23(b)(4) to clarify that while a nursing care plan is needed for every patient, the care plan should reflect the needs of the patient and the nursing care to be provided to meet those needs. In response to a comment, CMS specifies that a nursing care plan is required for hospital inpatients, but also may be appropriate, in some instances, for hospital outpatients. CMS notes its expectation that a nursing care plan is initiated and implemented in a timely manner, include patient goals as part of the patient’s nursing care assessment and, as appropriate, physiological and psychosocial factors (such as specific physical limitations and available support systems), physical and behavioral health comorbidities, and patient discharge planning. Moreover, it should be consistent with the plan for the patient’s medical care and demonstrate evidence of reassessment of the patient’s nursing care needs, response(s) to nursing interventions, and, as needed, revisions to the plan.

CMS also finalizes its proposal in §482.23(b)(6) to clarify that *all* licensed nurses who provide services in the hospital must adhere to the policies and procedures of the hospital. In addition, the director of nursing must provide for the adequate supervision and evaluation of the clinical activities of *all* nursing personnel (that is, all licensed nurses and any non-licensed personnel such as nurse aides, orderlies, or other nursing support personnel who are under the direction of the nursing service) which occur within the responsibility of the nursing service, regardless of the mechanism through which those personnel are obtained (hospital employee, contract, lease, other agreement, or volunteer). In the preamble, CMS states that while there are a variety of arrangements under which hospitals obtain the services of licensed nurses, ensuring the health and safety of patients requires that: 1) all nurses know and adhere to the policies and procedures of the hospital and 2) there be adequate supervision and evaluation of the clinical activities of all

nursing personnel who provide services that occur within the responsibility of the nursing service. CMS expects non-licensed personnel to be supervised by a licensed nurse.

Commenters expressed particular concern about the removal of the word “bedside” under §482.23(b), as commenters believed that this would create confusion in certain inpatient departments and asked that CMS clarify that each hospital or nursing home unit should ensure that nurse staffing should be immediately available, when needed. CMS, in response, notes that a RN must be available to care for any patient, as determined by the needs of the patient and hospital policy. On the other hand, CMS points out that there are some outpatient services where it might not be necessary to have an RN physically present, such as an off-campus outpatient department where radiology services are provided. CMS does agree with the comment that the approval of any nursing service policy falls under the authority of the hospital’s nursing leadership, rather than “medical staff”. CMS also notes that it mostly received positive comments about the requirement under §482.23(b)(4), which requires that the nursing care plan, which is needed for every patient, reflect the needs of the patient and the nursing care to be provided to meet those needs. CMS notes after review of its guidance that nursing care plans appropriately, in most instances, apply only to inpatients. It urges hospitals, however, to review their policies and procedures in this area to determine if there are outpatients where a nursing care plan could be beneficial.

After consideration of the comments CMS received on the proposed rule, it finalizes §482.23 as proposed with the exception of the proposed requirement at §482.23(b)(7)(iii), which it revised in response to comments by replacing “medical staff” with “director of nursing”.

7. Medical Record Services (§482.24)

CMS did not finalize the proposed changes to the medical records documentation requirements at §482.24. Commenters were concerned that the medical records documentation revisions would be unduly burdensome and confusing regarding distinctions between the requirements for inpatients versus outpatients, as well as other issues including EHR interoperability. CMS agreed with these concerns.

In the proposed rule, CMS had noted concerns about the regulatory language in §482.24, as it appeared to apply only to inpatients, particularly with the use of terms such as “admission,” “hospitalization,” and “discharge.” It had also emphasized that the Medicare hospital CoPs apply to services being provided to all patients, *regardless of insurer*, and to both inpatients and outpatients of a hospital.

CMS proposed the following changes:

- (1) Revisions to §482.24(c) to require that the content of the medical record contain information to justify *all* admissions and continued hospitalizations, support the *diagnoses*, describe the patient's progress and response to medications and services, and *document all inpatient stays and outpatient visits to reflect all services provided to the patient* [proposed changes noted in italics].

- (2) Revisions to subparagraph §482.24(c)(4)(ii), to include “all diagnoses specific to each inpatient stay and outpatient visit, ” which would include specifying any admitting diagnoses.
- (3) Revisions to §482.24(c)(4)(iv), so that the content of the record would have to include documentation of complications, hospital-acquired conditions, healthcare associated infections, and adverse reactions to drugs and anesthesia. (It currently states “documentation of complications, hospital acquired infections, and unfavorable reactions to drugs and anesthesia.”)
- (4) Revisions to §482.24(c)(4)(vi), that would add “progress notes... interventions, responses to interventions...” to the required documentation of “practitioners’ orders” to emphasize the necessary documentation for both inpatients and outpatients. The phrase “to reflect all services provided to the patient” would be added to the text so that the provision would say that the content of the record must contain “all practitioners' progress notes and orders, nursing notes, reports of treatment, interventions, responses to interventions, medication records, radiology and laboratory reports, and vital signs and other information necessary to monitor the patient's condition and to reflect all services provided to the patient.”
- (5) Revisions to current §482.24(c)(4)(vii), to require that all patient medical records document discharge and transfer summaries with outcomes of all hospitalizations, disposition of cases, and provisions for follow-up care for all inpatient and outpatient visits to reflect the scope of all services received by the patient.
- (6) Revisions to §482.24 (c)(4)(viii) so that the content of the medical record would contain final diagnoses with completion of medical records within 30 days following all inpatient stays, and within 7 days following all outpatient visits. The current requirement is for “[f]inal diagnosis with completion of medical records within 30 days following discharge.”

8. Infection Prevention and Control and Antibiotic Stewardship Programs (§482.42)

CMS finalizes revisions to §482.42, with modifications, to clarify existing requirements related to infection control and to update the regulatory language to reflect state of the art practices and terminology. This section includes requirements that hospitals develop and maintain an antibiotic stewardship program to improve antibiotic prescribing practices and to curb the risk for potentially life-threatening antibiotic resistant infections.

CMS finalizes a change to the title of this CoP to “Infection prevention and control and antibiotic stewardship programs.” CMS believes that this change emphasizes the importance of preventing infections and combatting antibiotic resistance and helps promote larger, cultural changes in hospitals. It also finalizes changes to the introductory paragraph of this section to require that a hospital’s infection prevention and control and antibiotic stewardship programs be active and hospital-wide for the surveillance, prevention, and control of hospital associated infections (HAIs) and other infectious diseases, and for the optimization of antibiotic use through stewardship. While these particular changes are new to the regulatory text, CMS notes, with the

exception of the new requirement for an antibiotic stewardship program, that these have been present in Interpretive Guidelines for hospitals since 2008.⁷

CMS also finalizes its proposal to incorporate the term “surveillance” into the text of the regulation, as it believes that the addition of this term will bring the regulation up to date by reflecting current terminology in the field.

CMS finalizes a new requirement that hospitals demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms.

In addition, CMS finalizes revisions, with modifications, to the language at §482.42(a) and §482.42(b) that addresses infection prevention program organization and policies, and antibiotic stewardship program organization and policies. CMS makes similar revisions for §485.640(a) and §485.640(b) that apply to CAHs.

Specifically, CMS makes the following revisions in the final rule:

- Revises and finalizes the language of §§482.42(a)(1) and 485.640(a)(1) to now require: “An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program. The selection process must include meaningful opportunity for input from members of the medical and nursing staffs.”
- Revises and finalizes the language of §§482.42(b)(1) and 485.640(b)(1) to now require: “An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed as the leader(s) of the antibiotic stewardship program. The selection process must include meaningful opportunity for input from members of the medical, nursing, and pharmacy staffs”.
- Revises and finalizes the language at §§ 482.42(b)(2)(iii) and 485.640(b)(2)(iii) to now require: “Documents any improvements, including sustained improvements, in proper antibiotic use”.

Some commenters expressed concern about the proposed rule’s reference to the Infectious Disease Society of America (IDSA) antibiotic stewardship program guidelines. Others expressed concern that these new provisions might require additional time to implement in Inpatient Rehabilitation Facilities (IRFs) and Long-Term Care Hospitals (LTCHs) beyond the standard 60 days. Commenters also urged CMS to be flexible in the implementation of these provisions for all hospitals, especially smaller hospitals and CAHs, due to the time and effort needed to fill leadership positions and develop their programs. Another commenter did not support the proposal to require that the leaders of the infection prevention and control and antibiotic

⁷ See A0747 at Appendix A - Survey Protocol, Regulations and Interpretive Guidelines for Hospitals http://cms.gov/manuals/Downloads/som107ap_a_hospitals.pdf.

stewardship programs be specifically appointed by the governing body of a hospital or CAH. One commenter urged CMS to modify the proposed standard regarding the demonstration of improvements in antibiotic stewardships noting that it can be difficult to demonstrate meaningful improvement over a short-period of time, particularly since numerous external factors contribute to resistance patterns that may not be related to the actions of the hospital.

In response, CMS notes that is not requiring that hospitals choose the IDSA guidelines for antibiotic stewardship programs specifically, only that they choose guidance from a nationally recognized source. CMS agrees that additional time may be needed beyond the standard 60 days for all facilities. Thus, the provisions regarding antibiotic stewardship will become effective and be enforced 6 months after the effective date of this final rule for all facilities. CMS also agrees that more flexibility is needed with how leaders of the infection prevention and control and antibiotic stewardship programs are chosen, and revises sections §§482.42(b)(1) and 485.640(b)(1), accordingly. In response to the language on demonstration of improvements in antibiotic stewardships, CMS modifies the regulatory language to provide more flexibility and acknowledge in its response that other external factors can negatively contribute to antibiotic resistance in the facility.

9. Technical Corrections

CMS finalizes its proposed technical changes, without modification. It received no comments on these changes.

Technical Amendments to §482.27(b)(7)(ii) and (b)(11). In the final rule “Medicare and Medicaid Programs; Hospital Conditions of Participation: Laboratory Services,” amending 42 CFR 482.27 (Aug. 24, 2007), CMS stated that hepatitis C virus (HCV) notification requirements for donors tested before February 20, 2008, would expire on August 24, 2015. Since the notification requirement period has expired, CMS removes §482.27(b)(11) and the “Applicability” and the corresponding requirements set out at §482.27(b)(7)(ii).

Corrected Reference in §482.58. CMS corrects an incorrect cross reference at §482.58(b)(6), which currently reads “Discharge planning (§483.20(e))”. Section 483.20(e) addresses coordination of the preadmission screening and resident review program and not discharge planning. Skilled nursing facility (SNF) requirements for discharge plans are at §483.20(l). CMS would correct the reference to read “Discharge summary (§483.20(l))”.

Removal of Inappropriate References to §482.12(c)(1). Several provisions in the hospital CoP incorrectly reference §482.12(c)(1), which lists the types of physicians and applies only to patients who are Medicare beneficiaries. Section 482.12(c) states that the governing body of the hospital must ensure that every Medicare patient is under the care of one of a list of practitioners (see 81 FR 39460 for this list). The reference to this “Medicare beneficiary-only” requirement in other provisions of the CoPs inappropriately links it to *all* patients and not Medicare beneficiaries exclusively. Section 1861(e)(4) of the Act provides that “every patient with respect to whom payment may be made under this title must be under the care of a physician except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under state

law.” In accordance with that provision, CMS has chosen to apply §482.12(c) to Medicare patients.

With the exception of a few provisions in the CoPs such as those directly related to §482.12(c) described here, *the remainder of the CoPs apply to all patients, regardless of payment source, and not just Medicare beneficiaries*. CMS provides examples, including that for the Nursing Services CoP at §482.23(c)(1), which requires all drugs and biologicals to 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. Since the CoPs clearly allow hospitals to determine which categories of practitioners would be responsible for the care of other patients, outside the narrow Medicare beneficiary restrictions of §482.12(c), this reference is inappropriate and unnecessarily restrictive of hospitals and their medical staffs to make these determinations based on state law and practitioner scope of practice. In order to clarify that these latter provisions apply to all patients and not only Medicare beneficiaries, CMS deletes any inappropriate references to §482.12(c). These include: §482.13(e)(5), (e)(8)(ii), (e)(14), and (g)(4)(ii) in the Patients’ Rights CoP; and §482.23(c)(1) and (3) in the Nursing Services CoP. With respect to all of these provisions, the reference to services provided under the order of a physician or other practitioner still apply.

CMS also notes that in the course of finalizing this rule, it discovered that it inadvertently failed to propose to delete an inappropriate reference to §482.12(c), which is contained in the current provision at §482.61(d) in the Special Medical Record Requirements for Psychiatric Hospitals CoP under the Special Requirements for Psychiatric Hospitals (regarding which hospital personnel may complete progress notes). CMS is also deleting this reference in this final rule, and believes this revision is a technical one and does not require notice and comment.

C. Provisions of the Proposed Regulations and Responses to Public Comments for Critical Access Hospitals (42 CFR 485)

1. Organizational structure (§485.627(b))

Existing rules governing the organizational structure of a CAH require, at §485.627(b)(1), disclosure of the names of the CAH’s owners, those with a controlling interest in the CAH, and any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest. CMS proposed to delete those requirements at §485.627(b)(1) because they are duplicative of requirements at §420.206 (regarding the provider enrollment process).

CMS notes that this proposal was also included in the Medicare and Medicaid Programs; Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction, Proposed Rule (83 FR 47685). CMS is finalizing this proposal in that final rule.

2. Periodic Review of Clinical Privileges and Performance (§485.631(d)(1) through (2))

Existing §485.641(b)(3) and (4) require a member of the CAH staff who is a doctor of medicine or osteopathy to evaluate the quality and appropriateness of the diagnosis and treatment furnished by non-physician providers at the CAH. Under those rules, the quality and appropriateness of the diagnosis and treatment furnished by physicians at the CAH must also be evaluated by: a hospital that is a member of the network (when applicable); a QIO or equivalent

entity; another appropriate and qualified entity identified in the state rural health care plan; or, in the case of distant-site telemedicine services under an agreement between the CAH and a distant-site hospital, the distant-site hospital; or, in the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under an agreement between the CAH and a distant-site telemedicine entity, one of the entities listed above.

CMS moves those provisions, without change, to §485.631(d) under a new standard, entitled “Periodic Review of Clinical Privileges and Performance, which it views as a more appropriate placement for the current provisions.

3. Provision of services Section 485.635(a)(3)(vii).

Existing §485.635(a)(3)(vii) requires that a CAH have in place procedures that ensure the nutritional needs of inpatients are met in accordance with recognized dietary practices and with the orders of the practitioner responsible for the care of the patients.

CMS finalizes its proposal to add flexibility to this requirement so that CAHs may also permit registered dietitians to order therapeutic diets for patients in accordance with state laws. The requirement, re-designated at §485.635(a)(3)(vi), would apply, as described in the preamble, to all qualified dietitians and any other clinically qualified nutrition professionals as long as such professionals meet the requirements of any applicable state laws, regulations or other professional standards. CMS outlined in the proposed rule the existing literature that supports the use of dietician professionals to assess a patient’s nutritional status, and to design and implement a nutritional treatment plan in consultation with the patient’s interdisciplinary care team. Some of that literature concludes that outcomes are improved, and costs are reduced with care by professional dietitians.

In addition, new paragraph (3)(vi) retains the existing requirement that the protection described at §483.25(i) applies to inpatients receiving post-CAH SNF care. The provision ensures that a patient maintains acceptable parameters of nutritional status (for example, body weight and protein levels), unless it is not possible because of the patient’s clinical condition, and receives a therapeutic diet when there is a nutritional problem.

Commenters were supportive of CMS’ efforts to allow clinicians to practice to the fullest extent of their credentials.

4. Provision of services Section 485.635(g).

CMS does not finalize its proposal to establish an explicit nondiscrimination standard applicable to CAHs, and is instead deferring to the non-discrimination requirements of section 1557 of the ACA section. This ACA provision prohibits health programs that receive federal assistance, such as Medicare and Medicaid, from excluding or denying beneficiaries’ participation based on their race, color, national origin, sex (including gender identity), age, or disability.

Under its proposal, the CAH was required to establish and implement a written policy prohibiting discrimination on the basis of race, color, religion, national origin, sex (including gender identity), sexual orientation, age, or disability. A CAH also was required to inform each patient (including the patient’s support person, where appropriate) of the right to be free from

discrimination in a language that the patient can understand and to inform the patient and/or their representative, about how to seek assistance if they encounter discrimination.

5. Infection prevention and control and antibiotic stewardship programs (new §485.640)

CMS finalizes its proposal to remove the current requirements at §§485.635(a)(3)(vi) and 485.62(b)(2) and add a new infection prevention and control and antibiotic stewardship CoP at §485.640 for CAHs. CMS states that existing standards for infection control do not reflect the current nationally recognized standards of practice for the prevention and elimination of healthcare-associated infections and for the appropriate use of antibiotics. These facility-wide infection prevention and control and antibiotic stewardship program are coordinated with the CAH QAPI program for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship.

Commenters noted that CAHs would need time, resources, flexibility, and support to adapt to the antibiotic stewardship requirements. As noted above, CMS is providing additional time for hospitals and CAH to comply with the antibiotic stewardship requirements – six months from the effective date of the final rule. It stresses, though, that while CAHs may face special challenges, antibiotic stewardship is no less important in this setting, and encourages CAHs to use the technical assistance available from their State Flex Program. It also encourages CAHs to utilize the infection control training and resources that are available through the Centers for Disease Control and Prevention (CDC) (<https://www.cdc.gov/infectioncontrol/training/index.html>).

6. Quality Assessment and Performance Improvement (QAPI) Program (§485.641)

CMS finalizes its proposal, with modifications, to revise §485.641 titled “Quality Assessment and Performance Improvement Program,” to establish new requirements for a QAPI program at a CAH. CMS states that this new requirement would replace the existing reactive annual evaluation and quality assurance review requirement with a proactive approach of a QAPI program. Such a program would allow a CAH to review its operating systems and processes of care to identify opportunities to improve patient health outcomes and prevent and reduce medical errors.

CMS reevaluated its proposed requirements and is withdrawing certain provisions that it believes are now unnecessarily prescriptive. This includes the proposed provision under paragraph (c)(1) through (6); paragraph (e); and paragraph (f)(2) through (3). These provisions had established governance and leadership requirements, performance improvement projects, and program data collection and analysis requirements.

In response to commenters concerns that it underestimated the time and effort it would take CAHs to implement a new QAPI program, CMS provides an extended timeframe for implementation. As finalized, the requirements at §485.641 must be implemented by 18 months after the effective date of this final rule. CMS also encourages CAHs to utilize the technical assistance and services for CAHs that are available through the State Flex Programs, including the Medicare Beneficiary Quality Improvement Project (MBQIP), supported by the Health Resources and Services Administration’s Federal Office of Rural Health Policy.

7. Technical Corrections

CMS corrects a typographical error in the regulations at §485.645 by correcting the word “provided” to “provide” in the lead first sentence. CMS also deletes an obsolete cross-reference to §482.12(c) in its revisions of the regulations text at §482.61(d).

D. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, CMS is required to provide 30-day notice in the *Federal Register* and to solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget for review and approval. CMS specifically solicits comment on the need for information collection, the accuracy of the agency’s burden estimates, the quality utility and clarity of the information to be collected, and any recommendations to minimize the burden on the affected parties. The costs of complying with these requirements are estimated by CMS and are incorporated in Table 18 below.

E. Regulatory Impact Analysis

CMS estimates that this final rule meets the threshold as “economically significant” (\$100 million or more in any one year), and therefore a regulatory impact analysis was conducted. The impact is estimated by CMS to include both costs as well as savings to hospitals and CAHs, which are in part offsetting. The budgetary impact of those reforms for which CMS estimates measurable economic effects is summarized in Table 18, duplicated below. This table incorporates both the costs of complying with information collection requirements (ICRs) as well as those costs attributed to the regulatory impact analysis (RIA).

Table 18 – Section-by-Section Economic Impact Estimates

Issue	Frequency	Number of Affected Entities	Estimated Net Costs (\$ millions)*
Hospitals		4,823	
• Patients’ rights (ICR)	One-time	4,823	Not estimated
• Nursing services (ICR)	Every 3 years	1,193	1
• Nursing services (ICR)	One-time	1,193	2
• Infection Prevention & Control and Antibiotic Stewardship (RIA)	One-time	4,823	20
	Recurring annually	482	-23
CAHs		1,353	
• QAPI (ICR)	Recurring annually	1,004	1
• Food and Dietary (RIA)	Recurring annually	677	-5

Issue	Frequency	Number of Affected Entities	Estimated Net Costs (\$ millions)*
• Infection Prevention & Control	One-time	1,353	6
		1,004	148
Infection Prevention & Control and Antibiotic Stewardship (RIA)	Recurring annually	501	-27

Note: This table includes entries only for those reforms for which CMS believes would have a measurable economic effect; includes estimates from ICRs and RIA. Negative costs indicate cost savings. * Amounts rounded to the nearest million.

For its estimates on the potential impacts of this final rule, CMS uses 4,823 hospitals and 1,353 CAHs that are certified by Medicare and/or Medicaid. The discussion below provides additional detail on the assumptions CMS used to derive cost and savings estimates on infection prevention and control and antibiotic stewardship, the issues with the largest effect on cost/savings' estimates.

Infection Prevention and Control. CMS assumes that each hospital will be required to review its current infection control program and compare it to the new requirements. CMS calculates a one-time cost of about \$20 million (\$4,192 cost per hospital times 4,823 hospitals). CMS assumes that a physician and a nurse on the infection control team will conduct this review and revision of the program and require 16 hours each to conduct this work. Each hospital will require 32 burden hours at a cost of \$4,192 (\$191 an hour for physician x 16 burden hours, and \$71 an hour for a nurse x 16 burden hours).

Antibiotic Stewardship. CMS assumes that each hospital will have an active antibiotic stewardship program, which will result in additional costs but be greatly offset by savings a hospital would achieve through such a program. CMS calculates that aggregate burden of implementing and maintaining an hospital antibiotic stewardship program would be about \$186 million, but offset by \$209 million in combined annual drug cost savings and patient cost savings. Combined this would result in \$23 million in recurring annual savings.

- Costs would include the leadership of a physician, clinical pharmacist, and a network data analyst (0.10, 0.25, and 0.05 full-time equivalents, respectively). CMS assumes that 10 percent of hospitals do not yet have programs that implement all of the CDC core elements. The annual labor cost for 10 percent of hospitals (\$386,800 x 482) would be about \$186 million.
- Savings would accrue from a decrease in inappropriate antibiotic use leading to overall decreased drug costs for a hospital. CMS' review of the literature showed significant savings through reduced hospital pharmacy costs. In addition, CMS believes that such a program would result in patient cost savings from decreases in patient length of stay and readmission rates. CMS notes that while these savings will accrue to patients, hospitals, and insurers, it was not able to allocate these savings to each group.

CMS uses similar assumptions to estimate the effect on CAHs. For infection prevention and control, CMS calculates a one-time cost of about \$5.7 million for CAHs. Similarly, CMS estimates that each CAH will have an active antibiotic stewardship program. It anticipates an annual labor cost of about \$89 million (the labor time associated with a physician, clinical pharmacist, and network data analyst) and that approximately 501 CAHs (or 37 percent) have not implemented an antibiotic stewardship program. It anticipates that costs will be offset by combined annual drug cost savings and patient cost savings of about \$116 million. Combined this would result in \$27 million in recurring annual savings for CAHs.