

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482, 484, and 485

[CMS-3317-P]

RIN 0938-AS59

Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the discharge planning requirements that Hospitals, including Long-Term Care Hospitals and Inpatient Rehabilitation Facilities, Critical Access Hospitals, and Home Health Agencies must meet in order to participate in the Medicare and Medicaid programs. The proposed rule would also implement the discharge planning requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on January 4, 2016.

ADDRESSES: In commenting, please refer to file code CMS-3317-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

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

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

2. *By regular mail.* You may mail written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3317-P, P.O. Box 8016, Baltimore, MD 21244-8016.

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

3. *By express or overnight mail.* You may send written comments to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3317-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier)

your written comments ONLY to the following addresses prior to the close of the comment period:

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

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

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

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members.

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

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

FOR FURTHER INFORMATION CONTACT:

Alpha-Banu Huq, (410) 786-8687.
Sheila C. Blackstock, (410) 786-1154.
Mary Collins, (410) 786-3189.
Scott Cooper, (410) 786-9465.
Jacqueline Leach, (410) 786-4282.
Lisa Parker, (410) 786-4665.

SUPPLEMENTARY INFORMATION:

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

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday

through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

Acronyms

Because of the many terms to which we refer by acronym in this proposed rule, we are listing the acronyms used and their corresponding meanings in alphabetical order below:

AAA	Area Agencies on Aging
ADA	Americans with Disabilities Act
ADRC	Aging and Disability Resources Centers
AHRQ	Agency for Healthcare Research and Quality
AO	Accrediting Organization
APRN	Advanced Practice Registered Nurse
CAH	Critical Access Hospital
CDC	Centers for Disease Control and Prevention
CfCs	Conditions for Coverage
CIL	Centers for Independent Living
CLAS	Culturally and Linguistically Appropriate Services in Health and Health Care
CMS	Centers for Medicare and Medicaid Services
COI	Collection of Information
CoPs	Conditions of Participation
DO	Doctor of Osteopathic Medicine
DRG	Diagnosis-Related Group
EACH	Essential Access Community Hospital
ECQM	Electronically Specified Clinical Quality Measures
EHR	Electronic Health Records
HHA	Home Health Agencies
HHS	Department of Health and Human Services
HIE	Health Information Exchange
ICR	Information Collection Requirements
IT	Information Technology
IRF	Inpatient Rehabilitation Facility
LTCH	Long-Term Care Hospital
MAP	Measure Applications Partnership
OASH	Office of the Assistant Secretary for Health
OMB	Office of Management and Budget
ONC	Office of the National Coordinator for Health Information Technology
PA	Physician Assistant
PAC	Post-Acute Care
PCP	Primary Care Provider
PDMP	Prescription Drug Monitoring Program
PRA	Paperwork Reduction Act
QAPI	Quality Assessment and Performance Improvement
RFA	Regulatory Flexibility Act
RIA	Regulatory Impact Analysis
RPCH	Rural Primary Care Hospital
SA	State Survey Agencies
SAMHSA	Substance Abuse and Mental Health Services Administration
SNF	Skilled Nursing Facility

Table of Contents

I.	Background
	A. Overview
	B. Legislative History
II.	Provisions of the Proposed Regulations
	A. Hospital Discharge Planning

1. Design (Proposed § 482.43(a))
2. Applicability (Proposed § 482.43(b))
3. Discharge Planning Process (Proposed § 482.43(c))
4. Discharge to Home (Proposed § 482.43(d))
5. Transfer of Patients to Another Health Care Facility (Proposed § 482.43(e))
6. Requirements For Post-Acute Care Services (Proposed § 482.43(f))
- B. Home Health Agency Discharge Planning
 1. Discharge Planning Process (Proposed § 484.58(a))
 2. Discharge or Transfer Summary Content (Proposed § 484.58(b))
- C. Critical Access Hospital Discharge Planning
 1. Design (Proposed § 485.642(a))
 2. Applicability (Proposed § 485.642(b))
 3. Discharge Planning Process (Proposed § 485.642(c))
 4. Discharge to Home (Proposed § 485.642(d)(1) through (3))
 5. Transfer of Patients To Another Health Care Facility (Proposed § 485.642(e))
- III. Collection of Information Requirements
 - A. ICRs Regarding Hospital Discharge Planning (§ 482.43)
 - B. ICRs Regarding Home Health Discharge Planning (§ 484.58)
 - C. ICRs Regarding Critical Access Hospital Discharge Planning (§ 485.642)
- IV. Regulatory Impact Analysis
 - A. Statement of Need
 - B. Overall Impact
 - C. Anticipated Effects
 1. Effects on Hospitals (including LTCHs and IRFs), CAHs, and HHAs
 2. Effects on Small Entities
 3. Effects on Patients and Medical Care Costs
 - D. Alternatives Considered
 - E. Cost to the Federal Government
 - F. Accounting Statement
- V. Response to Comments

I. Background

A. Overview

Discharge planning is an important component of successful transitions from acute care hospitals and post-acute care (PAC) settings. The transition may be to a patient's home (with or without PAC services), skilled nursing facility, nursing home, long term care hospital, rehabilitation hospital or unit, assisted living center, substance abuse treatment program, hospice, or a variety of other settings. The location to which a patient may be discharged should be based on the patient's clinical care requirements, available support network, and patient and caregiver treatment preferences and goals of care.

Although the current hospital discharge planning process meets the needs of many inpatients released from the acute care setting, some discharges result in less-than-optimal outcomes for patients including complications and adverse events that lead to hospital readmissions. Reducing avoidable

hospital readmissions and patient complications presents an opportunity for improving the quality and safety of patient care while lowering health care costs.

Patients' post-discharge needs are frequently complicated and multifactorial, requiring a significant level of on-going planning, coordination, and communication among the health care practitioners and facilities currently caring for a patient and those who will provide post-acute care for the patient, including the patient and his or her caregivers. The discharge planning process should ensure that patients and, when applicable, their caregivers, are properly prepared to be active partners and advocates for their healthcare and community support needs upon discharge from the hospital or PAC setting. Yet patients and their caregivers frequently are not meaningfully involved in the discharge planning process and are unable to name their diagnoses; list their medications, their purpose, or the major side effects; cannot explain their follow-up plan of care; or articulate their treatment preferences and goals of care. For patients who require PAC services, the discharge planning process should ensure that the transition from one care setting to another (for example, from a hospital to a skilled nursing facility or to home with help from a home health agency or community-based services provider (or both) is seamless. The receiving PAC facilities or organizations should have the necessary information and be prepared to assume responsibility for the care of the patient. When patients or receiving facilities or organizations do not have key information such as the information previously mentioned, they are less able to implement the appropriate post-discharge treatment plans. This puts patients at risk for serious complications and increases their chances of being re-hospitalized.

We also believe that hospitals and critical access hospitals (CAHs) should improve their focus on psychiatric and behavioral health patients, including patients with substance use disorders. While the current discharge planning requirements as well as those proposed in this rule include this subset of patients, we believe the special discharge planning needs of these patients are sometimes overlooked. We encourage hospital and CAHs to take the needs of psychiatric and behavioral health patients into consideration when planning discharge and arranging for PAC and community services. With these patients specifically, and just as we believe it should be with other types

of patients being discharged, we believe hospitals and CAHs must:

- Identify the types of services needed upon discharge, including options for tele-behavioral health services as available and appropriate;
- Identify organizations offering community services in the psychiatric hospital or unit's community, and demonstrate efforts to establish partnerships with such organizations; arrange, as applicable, for the development and implementation of a specific psychiatric discharge plan for the patient as part of the patient's overall discharge plan; and
- Coordinate with the patient for referral for post-acute psychiatric or behavioral health care, including transmitting pertinent information to the receiving organization as well as making recommendations about the post-acute psychiatric or behavioral health care needed by the patient.

We have also found that not having a thorough understanding of available community services can impact the discharge planning process. If the discharge planning team and patients or their caregivers are not aware of the full range of post-hospital services available, including non-medical services and supports, patients may be sent to care settings that are inappropriate, ineffective, or of inadequate quality. The lack of consistent collaboration and teamwork among health care facilities, patients, their families, and relevant community organizations may negatively impact selection of the best type of patient placement, leading to less than ideal patient outcomes and unnecessary re-hospitalizations. When planning transitions, hospitals should consult with Aging and Disability Resource Centers (ADRCs) (as defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3002)), or Area Agencies on Aging (AAAs) (also defined in section 102 of the Older Americans Act of 1965 (42 U.S.C. 3002)) and Centers for Independent Living (CILs) (as defined in section 702 of the Rehabilitation Act of 1973 (29 U.S.C. 796a)), or Substance Abuse Mental Health Services Administration's (SAMHSA's) treatment locator, or any combination of the centers or associations. ADRCs, AAAs, and CILs are required by federal statute to help connect individuals to community services and supports, and many of these organizations already help chronically impaired individuals with transitions across settings, including transitions from hospitals and PAC settings back home. Ongoing communication with a feedback loop among health care practitioners and

relevant community organizations in all patient care settings would assist in better patient transitions, but this level of communication has not been consistently achieved among the numerous health care settings within communities across the country. It is estimated that one third of re-hospitalizations might be avoided with improved comprehensive transitional care from hospital to community.¹

We believe the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185) that require hospitals, including but not limited to acute care hospitals, CAHs and certain PAC providers including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), home health agencies (HHAs), and skilled nursing facilities (SNFs), to take into account quality measures and resource use measures to assist patients and their families during the discharge planning process will encourage patients and their families to become active participants in the planning of their transition to the PAC setting (or between PAC settings). This requirement will allow patients and their families' access to information that will help them to make informed decisions about their post-acute care, while addressing their goals of care and treatment preferences. Patients and their families that are well informed of their choices of high-quality PAC providers, including providers of community services and supports, may reduce their chances of being re-hospitalized.

B. Legislative History

The IMPACT Act requires the standardization of PAC assessment data that can be evaluated and compared across PAC provider settings, and used by hospitals, CAHs, and PAC providers, to facilitate coordinated care and improved Medicare beneficiary outcomes. Section 2 of the IMPACT Act added new section 1899B to the Social Security Act (Act). That section states that the Secretary of the Department of Health and Human Services (the Secretary) must require PAC providers (that is, HHAs, SNFs, IRFs and LTCHs) to report standardized patient assessment data, data on quality measures, and data on resource use and other measures. Under section 1899B(a)(1)(B) of the Act, patient

assessment data must be standardized and interoperable to allow for the exchange of data among PAC providers and other Medicare participating providers or suppliers. Section 1899B(a)(1)(C) of the Act requires the modification of existing PAC assessment instruments to allow for the submission of standardized patient assessment data to enable comparison of this assessment data across providers. The IMPACT Act requires that assessment instruments be modified to utilize the standardized data required under section 1899B(b)(1)(A) of the Act, no later than October 1, 2018 for SNFs, IRFs, and LTCHs and no later than January 1, 2019 for HHAs. The statutory timing varies for the standardized assessment data described in subsection (b), data on quality measures described in subsection (c), and data on resource use and other measures described in subsection (d) of section 1899B. We currently are developing additional public guidance and we note that many of these PAC provisions are being addressed in separate rulemakings. More information can be found on the CMS Web site at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html>.

Section 1899B(j) of the Act requires that we allow for stakeholder input, such as through town halls, open door forums, and mailbox submissions, before the initial rulemaking process to implement section 1899B. To meet this requirement, we provided the following opportunities for stakeholder input: (a) We convened a technical expert panel (TEP) to gather input on three cross-setting measures identified as potential measures to the requirements of the IMPACT Act, that included stakeholder experts and patient representatives on February 3, 2015; (b) we provided two separate listening sessions on February 10th and March 24, 2015 on the implementation of the IMPACT Act, which also gave the public the opportunity to give CMS input on their current use of patient goals, preferences, and health assessment information in assuring high quality, person-centered and coordinated care enabling long-term, high quality outcomes; (c) we sought public input during the February 2015 ad hoc Measure Applications Partnership (MAP) process regarding the measures under consideration with respect to IMPACT Act domains; and (d) we implemented a public mail box for the submission of comments in January 2015 located at PACQualityInitiative@cms.hhs.gov. The CMS public mailbox

can be accessed on our PAC quality initiatives Web site: <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014-and-Cross-Setting-Measures.html>. Lastly, we held a National Stakeholder Special Open Door Forum to seek input on the measures on February 25, 2015.

Section 1899B(i) of the Act, which addresses discharge planning, requires the modification of the Conditions of Participation (CoPs) and subsequent interpretive guidance applicable to PAC providers, hospitals, and CAHs at least every 5 years, beginning no later than January 1, 2016. These regulations must require that PAC providers, hospitals, and CAHs take into account quality, resource use, and other measures under subsections (c) and (d) of section 1899B in the discharge planning process.

This proposed rule would implement the discharge planning requirements mandated in section 1899B(i) of the IMPACT Act by modifying the discharge planning or discharge summary CoPs for hospitals, CAHs, IRFs, LTCHs, and HHAs. The IMPACT Act identifies LTCHs and IRFs as PAC providers, but the hospital CoPs also apply to LTCHs and IRFs since these facilities, along with short-term acute care hospital, are classifications of hospitals. All classifications of hospitals are subject to the same hospital CoPs. Therefore, these PAC providers (including freestanding LTCHs and IRFs) are also subject to the proposed revisions to the hospital CoPs. Proposed discharge planning requirements for SNFs are addressed in the proposed rule, "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities" (80 FR 42167, July 16, 2015) at <https://www.federalregister.gov/articles/2015/07/16/2015-17207/medicare-and-medicaid-programs-reform-of-requirements-for-long-term-care-facilities>. Compliance with these requirements will be assessed through on-site surveys by the Centers for Medicare & Medicaid Services (CMS), State Survey Agencies (SAs) or Accrediting Organization (AOs) with CMS-approved Medicare accreditation programs.

II. Provisions of the Proposed Regulations

A. Hospital Discharge Planning

Various sections of the Act list the requirements that each provider must meet to be eligible for Medicare and Medicaid participation. Each statutory provision also specifies that the Secretary may establish other

¹ (Coleman E, Parry C, Chambers S, Min S: The Care Transitions Intervention *Arch Intern Med*. 166 (2006): 1822–1828. and Naylor M, McCauley K: The effects of a discharge planning and home follow-up intervention on elders hospitalized with common medical and surgical cardiac conditions. *J Cardiovascular Nurs*. 14 (1999): 44–54.)

requirements as necessary in the interest of the health and safety of patients. The Medicare CoPs and Conditions for Coverage (CFCs) set forth the federal health and safety standards that providers and suppliers must meet to participate in the Medicare and Medicaid programs. The purposes of these conditions are to protect patient health and safety and to ensure that quality care is furnished to all patients in Medicare and Medicaid-participating facilities. In accordance with section 1864 of the Act, CMS uses state surveyors to determine whether a provider or supplier subject to certification qualifies for an agreement to participate in Medicare. However, under section 1865 of the Act, providers and suppliers subject to certification may instead elect to be accredited by private accrediting organizations whose Medicare accreditation programs have been approved by CMS as having standards and survey procedures that meet or exceed all applicable Medicare requirements.

Section 1861(e) of the Act defines the term “hospital” and paragraphs (1) through (8) of this section list the requirements that a hospital must meet to be eligible for Medicare participation. Section 1861(e)(9) of the Act specifies that a hospital must also meet other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution. In addition, section 1861(e)(6)(B) of the Act requires that a hospital have a discharge planning process that meets the discharge planning requirements of section 1861(ee) of the Act.

Under section 1861(e) of the Act, the Secretary has established in regulation at 42 CFR part 482 the requirements that a hospital must meet to participate in the Medicare program. The hospital CoPs are found at § 482.1 through § 482.66. Section 1905(a) of the Act provides that Medicaid payments may be applied to hospital services. Regulations at § 440.10(a)(3)(iii) require hospitals to meet the Medicare CoPs to qualify for participation in the Medicaid program.

The current hospital discharge planning requirements at § 482.43, “Discharge planning,” were originally published on December 13, 1994 (59 FR 64141), and were last updated on August 11, 2004 (69 FR 49268). Under the current discharge planning requirements, hospitals must have in effect a discharge planning process that applies to all inpatients. The hospital must also have policies and procedures specified in writing. Over the years, we have made continuous efforts to reduce

patient readmissions by strengthening and modernizing the nation’s health care system to provide access to high quality care and improved health at lower cost. Since 2004, there has been a growing recognition of the need to make discharge from the hospital to another care environment safer, and to reduce the rise in preventable and costly hospital readmissions, which are often due to avoidable adverse events. As a result of our overall efforts, we refined the discharge planning regulations in 2004 (69 FR 49268) and updated the interpretive guidance in 2013 (Pub. L. 100–07, State Operations Manual, Appendix A: http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf). We refer readers to the discharge planning section, “Condition of Participation for Discharge Planning”, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_a_hospitals.pdf. As stated in this section of the State Operations Manual, “Hospital discharge planning is a process that involves determining the appropriate post-hospital discharge destination for a patient; identifying what the patient requires for a smooth and safe transition from the hospital to his/her discharge destination; and beginning the process of meeting the patient’s identified post-discharge needs.”

Subsequently, the IMPACT Act was signed on October 6, 2014, and directs the Secretary to publish regulations to modify CoPs and interpretive guidance to require PAC providers, hospitals and CAHs take into account quality, resource use, and other measures required by the IMPACT Act to assist hospitals, CAHs, PAC providers, patients, and the families of patients with discharge planning, and to also address the patient’s treatment preferences and goals of care. In light of these concerns, our continued efforts to reduce avoidable hospital readmission, and the IMPACT Act requirements, we are proposing to revise the hospital discharge planning requirements.

The current discharge planning identification process at § 482.43(a) requires hospitals to identify patients for whom a discharge plan is necessary, but this does not necessarily lead to a discharge plan. The regulation does not specify criteria for such identification, leading to variation across acute care hospital settings as to how they approach this task. Some hospitals use self-developed or industry-generated criteria for identifying patients who may be in need of a discharge plan. Others use pre-determined clinical factors such as age, co-morbidities, previous

hospitalizations, and available social support systems to identify patients who may need a discharge plan. Additionally, hospitals use any number of other factors such as physician preference, nursing, social work and case management experience and history, current workload, and common practice to develop the discharge plan. Finally, some hospitals develop discharge plans for every inpatient, regardless of any of the factors previously mentioned. As a result of these and other differences between hospitals, there is considerable variation in the extent to which there are successful transitions from acute care hospitals.

Similarly, the current requirements for a discharge planning evaluation of a patient, at § 482.43(b), after he or she is initially identified as potentially needing post-hospital services also do not guarantee the development of a discharge plan.

Hospital patients discharged back to their home may be given literature to read about medication usage and required therapies; prescriptions for post-hospital medications and supplies; and referrals to post-hospital resources. This approach does not adequately reinforce the necessary skills that patients, their caregivers, and support persons need to meet post-hospital clinical needs. Inadequate patient education has led to poor outcomes, including medication errors and omissions, infection, injuries, worsening of the initial medical condition, exacerbation of a different medical condition, and re-hospitalization.² Lack of patient education concerning medicine storage, disposal, and use may also be a factor in overdoses, substance use disorders and diversion of controlled substances.³

We also note there has been confusion in the hospital setting regarding the implementation requirement in the current discharge planning CoP. As stated at current § 482.43(c)(3), the hospital must arrange for the initial implementation of the patient’s discharge plan. The level of implementation of this standard varies widely, leading to inconsistent transitions from the acute care hospital. We believe that providing more specific

² (Calkins D et al.: Patient-Physician Communication at Hospital Discharge and patient’s Understanding of the Postdischarge Treatment Plan, *Arch Intern Med*, 157 (1997): 1026–1030. Minott J: Reducing Hospital Readmissions. Academy of Health. < http://www.academyhealth.org/files/publications/Reducing_Hospital_Readmissions.pdf > Accessed August 23, 2011).

³ http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4077453/pdf/theoncologist_1471.pdf.

requirements to hospitals on what actions they must take prior to the patient's discharge or transfer to a PAC setting would lead to improved transitions of care and patient outcomes.

We propose to revise the existing requirements in the form of six standards at § 482.43. The most notable revision would be to require that all inpatients and specific categories of outpatients be evaluated for their discharge needs and have a written discharge plan developed. Many of the current discharge planning concepts and requirements would be retained, but revised to provide more clarity. We also propose to require specific discharge instructions for all patients. At present, hospitals have some discretion and not every patient receives specific, written instructions.

We have reviewed the available literature on readmissions and sought to understand the various factors that influence the causes of avoidable readmissions. We recognize that much evidence-based research has been done to identify interventions that reduce readmissions of individuals with specific characteristics or conditions such as the elderly, cardiac patients, and patients with chronic conditions.

We propose to continue our efforts to reduce patient readmissions by improving the discharge planning process that would require hospitals to take into account the patient's goals and preferences in the development of their plans and to better prepare patients and their caregiver/support person(s) (or both) to be active participants in self-care and by implementing requirements that would improve patient transitions from one care environment to another, while maintaining continuity in the patient's plan of care. The following is a discussion of each of the proposed standards.

We propose at § 482.43, Discharge planning, to require that a hospital have a discharge planning process that focuses on the patient's goals and preferences and on preparing patients and, as appropriate, their caregivers/support person(s) to be active partners in their post-discharge care, ensuring effective patient transitions from hospital to post-acute care while planning for post-discharge care that is consistent with the patient's goals of care and treatment preferences, and reducing the likelihood of hospital readmissions.

1. Design (Proposed § 482.43(a))

In newly proposed § 482.43(a), we propose to establish a new standard, "Design", and would require that hospital medical staff, nursing

leadership, and other pertinent services provide input in the development of the discharge planning process. We also propose to require that the discharge planning process be specified in writing and be reviewed and approved by the hospital's governing body. We would expect that the discharge planning process policies and procedures would be developed and reviewed periodically by the hospital's governing body.

2. Applicability (Proposed § 482.43(b))

We propose to revise the current requirement at § 482.43(a), which requires a hospital to identify those patients for whom a discharge plan is necessary. At proposed § 482.43(b), "Applicability," we would require that many types of patients be evaluated for post discharge needs. We would require that the discharge planning process apply to all inpatients, as well as certain categories of outpatients, including, but not limited to patients receiving observation services, patients who are undergoing surgery or other same-day procedures where anesthesia or moderate sedation is used, emergency department patients who have been identified by a practitioner as needing a discharge plan, and any other category of outpatient as recommended by the medical staff, approved by the governing body and specified in the hospital's discharge planning policies and procedures. We believe that the aforementioned categories of patients would benefit from an evaluation of their discharge needs and the development of a written discharge plan.

3. Discharge Planning Process (Proposed § 482.43(c))

We propose at § 482.43(c), "Discharge planning process," to require that hospitals implement a discharge planning process to begin identifying, early in the hospital stay, the anticipated post-discharge goals, preferences, and needs of the patient and begin to develop an appropriate discharge plan for the patients identified in proposed § 482.43(b). The average length of stay in the hospital setting has decreased significantly since the current discharge planning standards were written. Timely identification of the patient's goals, preferences, and needs and development of the discharge plan would reduce delays in the overall discharge process. We propose to require that the discharge plan be tailored to the unique goals, preferences and needs of the patient. For example, based on the anticipated discharge needs, a discharge plan in the early

stages of development for a young healthy patient could possibly be as concise as a plan to provide instructions on follow-up appointments, and information on the warning signs and symptoms which may indicate the need to seek medical attention. On the other hand, the discharge needs of patients with co-morbidities, complex medical or surgical histories (or both), with mental health or substance use disorders (including indications of opioid abuse), socio-economic and literacy barriers, and multiple medications would require a more extensive discharge plan that takes into account all of these factors and the patient's treatment preferences and goals of care. As previously discussed, patient referrals to or consultation with community care organizations will be a key step, for some, in assuring successful patient outcomes. Therefore, we believe that discharge planning for patients is a process that involves the consideration of the patient's unique circumstances, treatment preferences, and goals of care, and not solely a documentation process.

We remind hospitals that they must continue to abide by federal civil rights laws, including Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act (ADA), and section 504 of the Rehabilitation Act of 1973, when developing a discharge planning process. To this end, hospitals should take reasonable steps to provide individuals with limited English proficiency or physical, mental, or cognitive and intellectual disabilities meaningful access to the discharge planning process, as required under Title VI of the Civil Rights Act, as implemented at 45 CFR 80.3(b)(2). Discharge planning would be of little value to patients who cannot understand or appropriately follow the discharge plans discussed in this rule. Without appropriate language assistance or auxiliary aids and services, discharge planners would not be able to fully involve the patient and caregiver/support person in the development of the discharge plan. Furthermore, the discharge planner would not be fully aware of the patient's goals for discharge.

Additionally, effective discharge planning will assist hospitals in complying with the U.S. Supreme Court's holding in *Olmstead v. L.C.* (527 U.S. 581 (1999)), which found that the unjustified segregation of people with disabilities is a form of unlawful discrimination under the ADA. We note that effective discharge planning may assist hospitals in ensuring that individuals being discharged who

would otherwise be entitled to institutional services, have access to community based services when: (a) Such placement is appropriate; (b) the affected person does not oppose such treatment; and (c) the placement can be reasonably accommodated.

We also remind hospitals, HHAs, and CAHs of existing state laws and requirements regarding discharge planning and their obligations to abide by these requirements. Additionally, they should also be aware of unique and innovative state programs focused on discharge planning.

We propose to combine and revise two existing requirements, § 482.43(b)(2) and § 482.43(c)(1), into a single requirement at § 482.43(c)(1), simplifying the requirement and incorporating some minor clarifying revisions. The resulting provision would require that a registered nurse, social worker, or other personnel qualified in accordance with the hospital's discharge planning policy, coordinate the discharge needs evaluation and the development of the discharge plan.

In proposed § 482.43(c)(2), we propose to establish a specific time frame during which discharge planning must begin. Section 482.43(a) currently requires a hospital to identify those patients who may need a discharge plan at an early stage of hospitalization. Ideally, discharge planning begins at the time of inpatient admission or outpatient registration. We understand that this is not always practicable. However, the current requirement might be considered too imprecise and could allow for discharge planning to be repeatedly delayed and perhaps several days to elapse before discharge planning is considered. Therefore, we would clarify the requirement by requiring that a hospital would begin to identify anticipated discharge needs for each applicable patient within 24 hours after admission or registration, and the discharge planning process is completed prior to discharge home or transfer to another facility and without unduly delaying the patient's discharge or transfer. If the patient's stay was less than 24 hours, the discharge needs would be identified prior to the patient's discharge home or transfer to another facility. This policy would not apply to emergency-level transfers for patients who require a higher level of care. However, while an emergency-level transfer would not need a discharge evaluation and plan, we would expect that the hospital would send necessary and pertinent information with the patient that is being transferred to another facility.

We propose to retain the current requirement set out at § 482.43(c)(4), and re-designate it with clarifications at § 482.43(c)(3). Currently we require that the hospital reassess the patient's discharge plan if there are factors that may affect continuing care needs or the appropriateness of the discharge plan. We propose at § 482.43(c)(3) to require that the hospital's discharge planning process ensure an ongoing patient evaluation throughout the patient's hospital stay or visit to identify any changes in the patient's condition that would require modifications to the discharge plan. The evaluation to determine a patient's continued hospitalization (or in other words, their readiness for discharge or transfer), is a current standard medical practice, and additionally is a current hospital CoP requirement at § 482.24(c). This proposed standard would expand upon the current regulation by requiring that the discharge evaluation be ongoing, during the patient's hospitalization or outpatient visit, and that any changes in a patient's condition that would affect the patient's readiness for discharge or transfer be reflected and documented in the discharge plan.

We propose a new requirement at § 482.43(c)(4) that the practitioner responsible for the care of the patient be involved in the ongoing process of establishing the patient's goals of care and treatment preferences that inform the discharge plan, just as they are with other aspects of patient care during the hospitalization or outpatient visit.

We propose to re-designate § 482.43(b)(4) as § 482.43(c)(5) to require, that as part of identifying the patient's discharge needs, the hospital consider the availability of caregivers and community-based care for each patient, whether through self-care, follow-up care from a community-based providers, care from a caregiver/support person(s), care from post-acute health care facilities or, in the case of a patient admitted from a long-term care or other residential care facility, care in that setting.

Hospitals should be consistent in how they identify and evaluate the anticipated post-discharge needs of the patient to support and facilitate a safe transition from one care environment to another. The proposed requirement at § 482.43(c)(5) would require hospitals to consider the patient's or caregiver's capability and availability to provide the necessary post-hospital care. As part of the on-going discharge planning process, hospitals would identify areas where the patient or caregiver/support person(s) would need assistance, and address those needs in the discharge

plan in a way that takes into account the patient's goals and preferences. In addition, we encourage hospitals to consider potential technological tools or methods, such as telehealth, to support the individual's health upon discharge.

We propose that hospitals consider the availability of and access to non-health care services for patients, which may include home and physical environment modifications including assistive technologies, transportation services, meal services or household services (or both), including housing for homeless patients. These services may not be traditional health care services, but they may be essential to the patient's ongoing care post-discharge and ability to live in the community. Hospitals should be able to provide additional information on non-health care resources and social services to patients and their caregiver/support person(s) and they should be knowledgeable about the availability of these resources in their community, when applicable. In addition, we encourage hospitals to consider the availability of supportive housing, as an alternative to homeless shelters that can facilitate continuity of care for patients in need of housing.

We would expect hospitals to be well informed of the availability of community-based services and organizations that provide care for patients who are returning home or who want to avoid institutionalization, including ADRCs, AAAs, and CILs, and provide information on these services and organizations when appropriate. ADRCs, AAAs, and CILs are required by federal statute to help connect individuals to community services and supports, and many of these organizations already help chronically impaired individuals with transitions across settings, including transitions from hospitals and PAC settings back home.

We encourage hospitals to develop collaborative partnerships with providers of community-based services to improve transitions of care that might support better patient outcomes. More information on these community-based services and organizations can be found in the following Web sites:

- For Information on Aging and Disability Resource Centers (ADRCs): <http://www.adrc-tae.acl.gov/tiki-index.php?page=HomePage>
- For information on Centers for Independent Living (CILs): <http://www.ilru.org/projects/cil-net/cil-center-and-association-directory>
- For information on Area Agencies on Aging (AAAs): http://www.aoa.acl.gov/AoA_Programs/OAA/

How_To_Find/Agencies/find_agencies.aspx

Accordingly, we propose that hospitals must consider the following in evaluating a patient's discharge needs, including but not limited to:

- Admitting diagnosis or reason for registration;
- Relevant co-morbidities and past medical and surgical history;
- Anticipated ongoing care needs post-discharge;
- Readmission risk;
- Relevant psychosocial history;
- Communication needs, including language barriers, diminished eyesight and hearing, and self-reported literacy of the patient, patient's representative or caregiver/support person(s), as applicable;
- Patient's access to non-health care services and community-based care providers; and
- Patient's goals and treatment preferences.

During the evaluation of a patient's relevant co-morbidities and past medical and surgical history, we encourage providers to consider using their state's Prescription Drug Monitoring Program (PDMP). PDMPs are state-run electronic databases used to track the prescribing and dispensing of controlled prescription drugs to patients. They are designed to monitor this information for suspected abuse or diversion and can give a prescriber or pharmacist critical information regarding a patient's controlled substance abuse history. This information can help prescribers and pharmacists identify high-risk patients who would benefit from early interventions (<http://www.cdc.gov/drugoverdose/pdmp/>).

In 2013, HHS prepared a report to Congress regarding enhancing the interoperability of State prescription drug monitoring programs with other technologies and databases used for detecting and reducing fraud, diversion, and abuse of prescription drugs. The report, prepared by The Office of the Assistant Secretary for Health (OASH), The Office of the National Coordinator for Health Information Technology (ONC), SAMHSA, and the Centers for Disease Control and Prevention (CDC) cites positive research that suggests that PDMPs reduce the prescribing of Schedule II opioid analgesics, lowers substance abuse treatment rates from opioids, and potentially reduces doctor shopping by increasing awareness among providers about at-risk patients. In addition, the report notes that surveys indicate that prescribers find PDMPs to be useful tools.

In addition to highlighting the potential benefits, the report finds that PDMPs encounter challenges in two areas: Legal and policy challenges and technical challenges. Specifically, the report points out issues, including significant interoperability problems, such as the lack of standard methods to exchange and integrate data from PDMPs to health IT systems. The report also describes legal and policy issues regarding who can use and access PDMPs, concerns with timely data transmission, concerns about the reliance on third parties to transmit data between states, and privacy and security challenges. In addition, the report discusses fiscal challenges, technical challenges including the lack of common technical standards, vocabularies, system-level access controls to share information with EHRs and pharmacy systems, data transmission concerns, and concerns with the current manner in which providers access the electronic PDMP database.

The report concludes that while PDMPs are promising tools to reduce the prescription drug abuse epidemic and improve patient care, addressing these existing challenges can greatly improve the ability of states to establish interoperability and leverage PDMPs to reduce fraud, diversion, and abuse of prescription drugs. The report offers several recommendations for addressing these challenges and we refer readers to the report in its entirety at the following Web site: https://www.healthit.gov/sites/default/files/fdasia1141report_final.pdf.

Given the potential benefits of PDMPs as well as some of the challenges noted above, we are soliciting comments on whether providers should be required to consult with their state's PDMP and review a patient's risk of non-medical use of controlled substances and substance use disorders as indicated by the PDMP report. As discussed in detail below we are also soliciting comments on the use of PDMPs in the medication reconciliation process.

We propose a new requirement at § 482.43(c)(6) that the patient and the caregiver/support person(s), be involved in the development of the discharge plan and informed of the final plan to prepare them for post-hospital care. Hospitals should integrate input from the patient, caregiver/support person(s) whenever possible. This proposed requirement provides the opportunity to engage the patient or caregiver/support person(s) (or both) in post-discharge decision making and supports the current patient rights requirement at § 483.13 in which the patient has the

right to participate in and make decisions regarding the development and implementation of his or her plan of care. This proposed requirement clarifies our current expectation regarding engaging caregivers/support persons in evaluating and planning a patient's discharge or transfer.

We propose a new requirement at § 482.43(c)(7) to require that the patient's discharge plan address the patient's goals of care and treatment preferences. During the discharge planning process, we would expect that the appropriate medical staff would discuss the patient's post-acute care goals and treatment preferences with the patient, the patient's family or their caregiver/support persons (or both) and subsequently document these goals and preferences in the medical record. We would expect these documented goals and treatment preferences to be taken into account throughout the entire discharge planning process.

We propose a new requirement at § 482.43(c)(8) to require that hospitals assist patients, their families, or their caregiver's/support persons in selecting a PAC provider by using and sharing data that includes but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. Furthermore, the hospital would have to ensure that the PAC data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences. We would also expect the hospital to document in the medical record that the PAC data on quality measures and resource use measures were shared with the patient and used to assist the patient during the discharge planning process.

We note that quality measures are defined in the IMPACT Act as measures relating to at least the following domains: Standardized patient assessments, including functional status, cognitive function, skin integrity, and medication reconciliation; by contrast, resource use measures are defined as including total estimated Medicare spending per individual, discharge to community, and measures to reflect all-condition risk-adjusted preventable hospital readmission rates. Accordingly, this proposed rule does not address or include further definition of these terms, which will be addressed and established in forthcoming regulations or other issuances. However, we advise providers to use other sources for information on PAC quality and resource use data, such as the data provided through the Nursing Home Compare and Home Health Compare Web sites, until the measures stipulated

in the IMPACT Act are finalized. Once these measures are finalized, providers will be required to use the measures as directed by the appropriate regulations and issuances.

As required by the IMPACT Act, hospitals must take into account data on quality measures and data on resource use measures of PAC providers during the discharge planning process. We would expect that the hospital would be available to discuss and answer patients and their caregiver's questions about their post-discharge options and needs.

In order to increase patient involvement in the discharge planning process and to emphasize patient preferences throughout the patient's course of treatment, we believe that hospitals must consider the aforementioned data in light of the patient's goals of care and treatment preferences. For example, the hospital could provide quality data on PAC providers that are within the patient's preferred geographic area. In another instance, hospitals could provide quality data on HHAs based on the patient's need for continuing care post-discharge and preference to receive this care at home. Hospitals should assist patients as they choose a high quality PAC provider. However, we would expect that hospitals would not make decisions on PAC services on behalf of patients and their families and caregivers and instead focus on person-centered care to increase patient participation in post-discharge care decision making. Person-centered care focuses on the patient as the locus of control, supported in making their own choices and having control over their daily lives.

We propose to re-designate and revise the current requirement set out at § 482.43(b)(5) at new § 482.43(c)(9). We would require that the patient's discharge needs evaluation and discharge plan be documented and completed on a timely basis, based on the patient's goals, preferences, strengths, and needs, so that appropriate arrangements for post-hospital care are made before discharge. This requirement would prevent the patient's discharge or transfer from being unduly delayed. We believe that in response to this requirement, hospitals would establish more specific time frames for completing the evaluation and discharge plans based on the needs of their patients and their own operations. All relevant patient information would be incorporated into the discharge plan to facilitate its implementation and the discharge plan must be included in the patient's medical record. The results of the evaluation must also be discussed

with the patient or patient's representative. Furthermore, we believe that hospitals will use their evaluation of the discharge planning process, with solicitation of feedback from other providers and suppliers in the community, as well as from patients and caregivers, to revise their timeframes, as needed. We encourage hospitals to make use of available health information technology, such as health information exchanges, to enhance the efficiency and effectiveness of their discharge process.

We propose to re-designate and revise the requirement at current § 482.43(e) at new § 482.43(c)(10). We would require that the hospital assess its discharge planning process on a regular basis. We propose to require that the assessment include ongoing review of a representative sample of discharge plans, including patients who were readmitted within 30 days of a previous admission, to ensure that they are responsive to patient discharge needs. This evaluation will assist hospitals to improve the discharge planning process. We believe the evaluation can be incorporated into the Quality Assessment and Performance Improvement (QAPI) process, although we have not explicitly required this coordination and solicit comments on doing so.

4. Discharge to Home (Proposed § 482.43(d))

We propose to re-designate and revise the current requirement at § 482.43(c)(5) (which currently requires that as needed, the patient and family or interested persons be counseled to prepare them for post-hospital care) as § 482.43(d), "Discharge to home," to require that the discharge plan include, but not be limited to, discharge instructions for patients described in proposed § 482.43(b) in order to better prepare them for managing their health post-discharge. The phrase "patients discharged to home" would include, but not be limited to, those patients returning to their residence, or to the community if they do not have a residence, who require follow-up with their primary care provider (PCP) or a specialist; HHAs; hospice services; or any other type of outpatient health care service. The phrase "patients discharged to home" would not refer to patients who are transferred to another inpatient acute care hospital, inpatient hospice facility or a SNF. We believe that our proposed revisions to the current requirement provide more clarity with respect to our proposed intent, and allow us to state more fully what we would expect in the way of better

preparing the patient or their caregiver(s)/support persons (or both) regarding post-discharge care.

We propose at § 482.43(d)(1) that discharge instructions must be provided at the time of discharge to patients, or the patient's caregiver/support person (s), (or both) who are discharged home or who are referred to PAC services. We are also proposing that practitioners/facilities (such as a HHA or hospice agency and the patient's PCP), receive the patient's discharge instructions at the time of discharge if the patient is referred to follow up PAC services. Discharge instructions can be provided to patients and their caregivers/support person(s) in different ways, including in paper and electronic formats, depending on the needs, preferences, and capabilities of the patients and caregivers. We would expect that discharge instructions would be carefully designed to be easily understood by the patient or the patient's caregiver/support person (or both). Resources on providing information that can be easily understood by patients are readily available and we refer readers to the National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care (the National CLAS Standards), for guidance on providing instructions in a culturally and linguistically appropriate manner at <https://www.thinkculturalhealth.hhs.gov/content/clas.asp>.

The National CLAS Standards are intended to advance health equity, improve quality, and help eliminate health care disparities by providing a blueprint for individuals and health and health care organizations to implement culturally and linguistically appropriate services.

In addition, as a best practice, hospitals should confirm patient or the patient's caregiver/support person's (or both) understanding of the discharge instructions. We recommend that hospitals consider the use of "teach-back" during discharge planning and upon providing discharge instructions to the patient. "Teach-back" is a way to confirm that a practitioner has explained to the patient what he or she needs to know in a manner that the patient understands. Training on the use of "teach-back" to ensure patient understanding of transition of care planning and appropriate medication use is readily available and we refer readers to the following resource for information on the use of "teach-back": <http://www.teachbacktraining.org>. At § 482.43(d)(2), we propose to set forth the minimum requirements for discharge instructions. The purpose of

discharge instructions is to guide patients and caregivers in the appropriate provision of post-discharge care. We propose to clarify our current requirement in § 482.43(c)(5) to require hospitals to provide instruction to the patient and his or her caregivers about care duties that they will need to perform in the patient's home. Instruction would be based on the specific needs of the patient as determined in the patient's discharge plan. This proposed requirement is consistent with the current requirement set forth at § 482.43(c)(5), which requires that "the patient and family members or interested persons must be counseled to prepare them for post-hospital care" We propose a new requirement at § 482.43(d)(2)(ii) that the discharge instructions include written information on the warning signs and symptoms that patients and caregivers should be aware of with respect to the patient's condition. The warning signs and symptoms might indicate a need to seek medical attention from an appropriate provider, depending on the severity level of the signs or symptoms. The written information would include instructions on what the person should do if these warning signs and symptoms present. Furthermore, the discharge instructions would include information about who to contact if these warning signs and symptoms present. This contact information may include practitioners such as the patient's primary care practitioner, the practitioner who was responsible for the patient's care while in the hospital or hospital emergency care departments, specialists, home health services, hospice services, or any other type of outpatient health care service.

At § 482.43(d)(2)(iii), we propose to require that the patient's discharge instructions include all medications prescribed and over-the-counter for use after the patient's discharge from the hospital. This should include a list of the name, indication, and dosage of each medication along with any significant risks and side effects of each drug as appropriate to the patient. Furthermore, we propose a new requirement at § 482.43(d)(2)(v) that the patient's medications would be reconciled. Medication reconciliation, according to the American Medical Association, is the process of making sense of patient medications and resolving conflicts between different sources of information to minimize harm and maximize therapeutic effects.⁴

Patients, especially those with comorbidities or chronic illnesses, often have multiple health care providers who prescribe medication. We note that interactions between specific prescription medications, as well as between specific prescription medications and over-the-counter medications, herbal preparations, and supplements are a growing concern, and are often not documented in the medical record. Medication reconciliation aims to improve patient safety by enhancing medication management.

In the context of this proposed rule, medication reconciliation would include reconciliation of the patient's discharge medication(s) as well as with the patient's pre-hospitalization/visit medication(s) (both prescribed and over-the-counter); comparing the medications that were prescribed before the hospital stay/visit and any medications started during the hospital stay/visit that are to be continued after discharge, and any new medications that patients would need to take after discharge. We would expect that any medication discrepancies (omissions, duplications, conflicts) would be corrected as part of the medication reconciliation process. Hospitals may utilize a number of approaches to ensure vigilant medication reconciliation. The medication reconciliation process should be a partnership between the patient and the healthcare team, be person-centered, and incorporate solutions to linguistic, cultural, socioeconomic, and literacy barriers. We are proposing that all patients have an accurate medication list prior to hospital discharge or transfer. The actual process used for medication reconciliation might vary among hospitals. We encourage hospitals to make use of current health information technology when establishing their medication reconciliation process. There are also many published resources available to assist hospitals with implementing this requirement. We refer readers to the following examples of resources that can be used to assist hospitals with the implementation of a medication reconciliation process:

- The Re-Engineered Discharge (RED) Toolkit (<http://www.ahrq.gov/professionals/systems/hospital/red/toolkit/index.html>) includes guidance on educating patients on diagnoses, self-care, and warning signs, overcoming language barriers, and conducting post-discharge telephone calls.
- The Hospital Guide to Reducing Medicaid Readmissions (<http://www.ahrq.gov/professionals/systems/hospital/medicaidreadmitguide/>

[index.html](#)) describes actions to improve transitions of care for vulnerable patients, including providing enhanced services for high risk patients.

- The AHRQ Health Literacy Universal Precautions Toolkit (<http://www.ahrq.gov/professionals/quality-patient-safety/quality-resources/tools/literacy-toolkit/>) contains tools on clear communication, the teach-back method, helping patients take medicine correctly, and encouraging questions.

- The SHARE Approach (<http://www.ahrq.gov/professionals/education/curriculum-tools/shareddecisionmaking/>) is a 5-step process for shared decision making that includes assessing patients' values and preferences.

- The Guide to Patient and Family Engagement in Hospital Quality and Safety (<http://www.ahrq.gov/professionals/systems/hospital/engagingfamilies/>) provides strategies to engage patients and families in discharge planning throughout their stay.

- Medications at Transitions and Clinical Handoffs (MATCH) Toolkit for Medication Reconciliation (<http://www.ahrq.gov/professionals/quality-patient-safety/patient-safety-resources/resources/match/match.pdf>) helps facilities establish a sound medication reconciliation process, evaluate the effectiveness of the existing processes, and identify and respond to any gaps.

- The MARQUIS (Multi-Center Medication Reconciliation Quality Improvement Study) (<https://innovations.ahrq.gov/qualitytools/multi-center-medication-reconciliation-quality-improvement-study-marquis-toolkit>) Toolkit helps facilities develop better ways for medications to be prescribed, documented, and reconciled accurately and safely at times of care transitions when patients enter and leave the hospital.

To enhance patient understanding of their medications, generic and proprietary names are expected to be provided for each medication, when available. The patient or caregiver/support person (or both) may be involved in reconciling medications and creating a new medication list. We would also expect that the medication reconciliation process would include a written list of all medications that a patient should take until further instructions are given by his or her practitioner at a follow-up appointment.

Furthermore, we would expect the medication reconciliation process to consider how patients would obtain their post-discharge medications. Many of the types of patients for whom discharge planning would be required under the proposed regulation are discharged from the hospital with

⁴ American Medical Association, "The Physician's Role in Medication Reconciliation," 2007.

medication prescriptions. Many patients do not realize that they will need to have prescriptions filled to continue the medication therapy that was started during their hospitalization/visit. A delay in obtaining necessary medication post-discharge could have significant adverse health effects. We believe patients or caregivers (or both) should be informed, in advance of the hospital discharge, of the anticipated need for filling outpatient (discharge) prescriptions, and have a plan on how they will obtain those medications. When necessary, assistance should be offered to the patient with identifying a pharmacy to fill the prescriptions post-discharge in a timely manner. In identifying a pharmacy, the hospital should consider whether the patient has prescription drug coverage that might require the patient to use a pharmacy within the drug plan's network and direct the patient appropriately.

As part of the medication reconciliation process, we encourage practitioners to consult with their state's PDMP. In section II.A.3 of this proposed rule we discuss the potential benefits as well as the challenges associated with the use of PDMPs. Given these potential benefits and challenges, we are soliciting comments on whether, as part of the medication reconciliation process, practitioners should be required to consult with their state's PDMP to reconcile patient use of controlled substances as documented by the PDMP, even if the practitioner is not going to prescribe a controlled substance.

We propose a new requirement at § 482.43(d)(2)(v) that written instructions, in paper or electronic format (or both), would be provided to the patient, and that the instructions would document follow-up care, appointments, pending and/or planned diagnostic tests, and any pertinent telephone numbers for practitioners that might be involved in the patient's follow-up care or for any providers/suppliers to whom the patient has been referred for follow-up care. The choice of format of the instructions should be based on patient and caregiver needs, preferences, and capabilities. Clear communication and discussions with the patient or other caregivers (or both) for follow-up care are an important determinant of patient outcomes following hospitalization. Hospitals should ascertain that the patient understands their discharge instructions. The major elements of any follow-up care would be required to be written so that the patient, caregiver/support person can refer to them post-hospitalization.

In addition to the patient receiving discharge instructions, it is important that the providers responsible for follow-up care with a patient (including the primary care provider (PCP) or other practitioner) receive the necessary medical information to support continuity of care. We therefore propose at § 482.43(d)(3) to require that the hospital send the following information to the practitioner (s) responsible for follow up care, if the practitioner has been clearly identified:

- A copy of the discharge instructions and the discharge summary within 48 hours of the patient's discharge;
- Pending test results within 24 hours of their availability;
- All other necessary information as specified in proposed § 482.43(e)(2).

We remind hospitals to provide this information in a manner that complies with all applicable privacy and security regulations.

Finally, we propose a new § 482.43(d)(4) to require, for patients discharged to home, that the hospital must establish a post-discharge follow-up process. Many studies have found that many patients experience major adverse health events post-discharge. These are often associated with medication compliance. As one example, a study, funded by Agency for Healthcare Research and Quality (AHRQ) and published in the *Annals of Internal Medicine*, found that one in five patients has a complication or adverse event after being discharged from the hospital.⁵ Another study using data from all Florida hospitals found that 7.86 percent of hospital admissions were potentially preventable, related to the original condition requiring admission, and occurred within the first several weeks after discharge.⁶ Post-discharge telephone call programs can improve patient safety and patient satisfaction, and may decrease the likelihood of post-discharge adverse events and hospital readmission. Post-discharge follow-up can help ensure that patients comprehend and adhere to their discharge instructions and medication regimens. Furthermore, post-discharge follow-up may identify problems in initiating follow-up care and detect complications of recovery early, resulting in early intervention, improved outcomes, and reduced re-hospitalization. A recent meta-analysis found a number of studies dealing with

post-discharge follow-up.⁷ This study "found that a home visit within three days, care coordination by a nurse (most frequently a registered nurse or advanced-practice nurse), and communication between the hospital and the primary care provider were components of transitional care that were significantly associated with reduced short-term readmission rates." We do not propose to specify the mechanism(s) or timing of the follow-up program so that hospitals can determine how to best meet the needs of their patient population. However, we note the importance of ensuring that hospitals follow-up, post-discharge, with their most vulnerable patients, including those with behavioral health conditions. We encourage hospitals to consider the use of innovative, low-cost post-discharge tools and technologies where health care providers and caregivers can ask simple questions that help identify at-risk individuals, that can be utilized for identifying those at risk for readmissions.

5. Transfer of Patients to Another Health Care Facility (Proposed § 482.43(e))

We propose to re-designate and revise the standard currently set out at § 482.43(d) as § 482.43(e), "Transfer of patients to another health care facility," by clarifying our expectations of the discharge and transfer of patients. We would continue to require that all hospitals communicate necessary information of patients who are discharged with transfer to another facility. The receiving facility may be another hospital (including an inpatient psychiatric hospital or a CAH) or a PAC facility. We believe that the transition of the patient from one environment to another should occur in a way that promotes efficiency and patient safety, through the communication of necessary information between the hospital and the receiving facility. We believe that the timely communication of necessary clinical information between health care providers support continuity of patient care, improves patient safety, and can reduce hospital readmissions. In 2014, many hospitals were using certified electronic health records that capture and standardize clinical data necessary to ensure safe transition in care delivery.

The current discharge requirement set out at § 482.43(d) requires hospitals that transfer patients to another facility to send with the patient (at the time of

⁵ Adverse Drug Events Occurring Following Hospital Discharge. Forster, et al., 2005.

⁶ Norbert Goldfield et al., "Identifying Potentially Preventable Readmissions," *Health Care Financing Review*, Fall 2008.

⁷ Kim J. Verhaegh et al., "Transitional Care Interventions Prevent Hospital Readmissions for Adults with Chronic Illnesses," *Health Affairs*, 33, no. 9 (2014).

transfer) the necessary medical information to the receiving facility. We know that transfers represent an increased period of risk for patients and that effective communication between care providers during transfers reduce this risk. In recognition of this, in August of 2011, the State of New Jersey mandated the use of a universal transfer form. Rhode Island and Massachusetts have also developed a continuity of care document or universal transfer form. The American Medical Directors Association has developed and recommends the use of a universal transfer form. Additionally, other tools and information are available from CMS (see <http://innovation.cms.gov/initiatives/CCTP/index.html>) and AHRQ (see <http://www.innovations.ahrq.gov/content.aspx?id=2577>) as well as through a number of professional organizations, including the National Transitions of Care Coalition (www.ntocc.org). Electronic health records could simplify the process of extracting necessary information when a resident is transferred to a nursing home and electronic Continuity of Care documents provide a standardized way to exchange critical information between providers. All of these tools and efforts are targeted at improving the communications between healthcare providers at the time of transfer. We do not propose to mandate a specific transfer form. However, we do propose to clarify our expectations regarding what constitutes the necessary medical information that must be communicated to a receiving facility to meet the patient's post-hospitalization health care goals, support continuity in the patient's care, and reduce the likelihood of hospital readmission. Moreover, we intend to align these data elements with the common clinical data set published in the "2015 Edition of Health Information Technology (Health IT) Certification Criteria, Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications" final rule (80 FR 62601, October 16, 2015). By aligning the data elements proposed in this proposed rule with the common clinical data set specified for the 2015 edition, we are seeking to ensure that hospitals can meet these requirements using certified health IT systems and existing standards. Therefore, we propose, at the minimum, the following information to be provided to a receiving facility:

- Demographic information, including but not limited to name, sex, date of birth, race, ethnicity, and preferred language;
- Contact information for the practitioner responsible for the care of

the patient and the patient's caregiver/support person(s);

- Advance directive, if applicable;
- Course of illness/treatment;
- Procedures;
- Diagnoses;
- Laboratory tests and the results of pertinent laboratory and other diagnostic testing;
- Consultation results;
- Functional status assessment;
- Psychosocial assessment, including cognitive status;
- Social supports;
- Behavioral health issues;
- Reconciliation of all discharge medications with the patient's pre-hospital admission/registration medications (both prescribed and over-the-counter);
- All known allergies, including medication allergies;
- Immunizations;
- Smoking status;
- Vital signs;
- Unique device identifier(s) for a patient's implantable device(s), if any;
- All special instructions or precautions for ongoing care, as appropriate;
- Patient's goals and treatment preferences; and
- All other necessary information to ensure a safe and effective transition of care that supports the post-discharge goals for the patient.

In addition to these proposed minimum elements, necessary information must also include a copy of the patient's discharge instructions, the discharge summary, and any other documentation that would ensure a safe and effective transition of care, as applicable.

While we are not proposing a specific form, format, or methodology for the communication of this information for all facilities, we strongly believe that those facilities that are electronically capturing information should be doing so using certified health IT that will enable real time electronic exchange with the receiving provider. By using certified health IT, facilities can ensure that they are transmitting interoperable data that can be used by other settings, supporting a more robust care coordination and higher quality of care for patients. We are soliciting comments on these proposed medical information requirements.

We note that HHS has a number of initiatives designed to encourage and support the adoption of health information technology and to promote nationwide health information exchange to improve the quality of health care. HHS believes all patients, their families, and their healthcare providers should

have consistent and timely access to health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care.⁸ ONC recently released a document entitled "Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap" (<https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-version-1.0.pdf>). The Roadmap identifies four critical pathways that health IT stakeholders should focus on now in order to create a foundation for long-term success: (1) Improve technical standards and implementation guidance for priority data domains and associated elements; (2) rapidly shift and align federal, state, and commercial payment policies from fee-for-service to value-based models to stimulate the demand for interoperability; (3) clarify and align federal and state privacy and security requirements that enable interoperability; and (4) align and promote the use of consistent policies and business practices that support interoperability and address those that impede interoperability, in coordination with stakeholders. In the near term, the roadmap focuses on ensuring individuals and providers across the continuum of care can send, receive, find and use priority data domains to improve health care quality and outcomes.

These initiatives are designed to encourage HIE among all health care providers, including those who are not eligible for the Electronic Health Record (EHR) Incentive Programs, and are designed to improve care delivery and coordination across the entire care continuum. Our revisions to this rule are intended to recognize the advent of electronic health information technology and to accommodate and support adoption of ONC certified health IT and interoperability standards. We believe that the use of this technology can effectively and efficiently help facilities and other providers improve internal care delivery practices, support the exchange of important information across care team members (including patients and caregivers) during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). For more information on guidance for ineligible providers, we direct stakeholders to the ONC guidance for EHR technology developers serving

⁸(HHS August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange.")

providers ineligible for the Medicare and Medicaid EHR Incentive Programs titled "Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments." (http://www.healthit.gov/sites/default/files/generalcert_exchangeguidance_final_8-9-13.pdf).

This guidance will be updated as new editions of certification criteria are released.

Additionally, we propose that the requirement and the timeframe for communicating necessary information for patients being transferred to another healthcare facility remain the same as in the current requirement. That is, hospitals would continue to be required to provide this information at the time of the patient's discharge and transfer to the receiving facility. Hospitals are encouraged to consider adapting or incorporating electronic tools (or both) to facilitate and streamline information that would fulfill the proposed discharge requirements to ensure a successful transfer of care. Hospitals are also encouraged to continue the practice of direct communication between the sending and receiving facilities. Clinician-to-clinician contact to discuss the patient's transfer, review information provided by the sending facility, and answer follow-up questions can help smooth the transfer process for the patient and the facilities. We believe that this direct communication is beneficial for all parties, and that this practice should continue to be used in addition to our proposed information-exchange requirements.

6. Requirements for Post-Acute Care Services (Proposed § 482.43(f))

We propose to re-designate and revise the requirements of current § 482.43(c)(6) through (8) at new § 482.43(f), "Requirements for post-acute care services." This standard is based in part on specific statutory requirements located at sections 1861(ee)(2)(H) and 1861(ee)(3) of the Act, with the addition of IRF and LTCH PAC providers in the regulatory text, in order to provide consistency with the IMPACT Act. The current regulation directs hospitals to provide a list of available Medicare-participating HHAs or SNFs to patients for whom home health care or PAC services are indicated. We are proposing that for patients who are enrolled in managed care organizations, the hospital must make the patient aware that they need to verify the participation of HHAs or SNFs in their network. If the hospital has information regarding which providers participate in the managed

care organization's network, it must share this information with the patient. The hospital must document in the patient's medical record that the list was presented to the patient. The patient or their caregiver/support persons must be informed of the patient's freedom to choose among providers and to have their expressed wishes respected, whenever possible. The final component of the retained provision would be the hospital's disclosure of any financial interest in the referred HHA or SNF. However, this section would be revised to include IRFs and LTCHs.

B. Home Health Agency Discharge Planning

Under the authority of sections 1861(m), 1861(o), and 1891 of the Act, the Secretary has established in regulations the requirements that a HHA must meet to participate in the Medicare program. Home health services are covered for qualifying elderly and people with disabilities who are entitled to benefits under the Hospital Insurance (Medicare Part A) and/or Supplementary Medical Insurance (Medicare Part B) programs. These services include skilled nursing care; physical, occupational, and speech therapy; medical social work; and home health aide services. Such services must be furnished by, or under arrangement with, an HHA that participates in the Medicare program and must be provided in the beneficiary's home.

On October 9, 2014, we published a proposed rule to reorganize the current CoPs for HHAs (79 FR 61163). The proposed requirements focused on the care delivered to patients by HHAs, reflected an interdisciplinary view of patient care, allowed HHAs greater flexibility in meeting quality care standards, and eliminated burdensome procedural requirements. The proposed changes were an integral part of our overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers. The October 9, 2014 proposed rule included a proposal to update the discharge or transfer summary CoPs for HHAs. Specifically, we proposed to specify the content of a discharge or transfer summary, and we proposed specific timelines for sending the discharge or transfer summary information to the follow-up care providers. We proposed these changes as two separate sections located at § 484.60(e) and § 484.110(a)(6).

The IMPACT Act was signed on October 6, 2014 and requires the Secretary to publish regulations to modify CoPs and to develop interpretive guidance to require that HHAs take into account quality measures, resource use measures, and other measures to assist PAC providers, patients, and the families of patients with discharge planning, and to address the treatment preferences of patients and caregivers/support person(s) and the patient's goals of care. As part of our efforts to update the current discharge planning/discharge summary requirements for several providers, we have revised the previously proposed discharge or transfer summary requirements for HHAs in this proposed rule to incorporate the requirements of the IMPACT Act. Therefore, we are withdrawing the proposed discharge summary content requirements at § 484.60(e) that were published in the October 9, 2014 proposed rule and are proposing to add a new standard at § 484.58 for discharge planning for HHAs.

The current regulations at § 484.48 require HHAs to prepare a discharge summary that includes the patient's medical and health status at discharge, include the discharge summary in the patient's clinical record, and send the discharge summary to the attending physician upon request. We propose to update the discharge summary requirements by requiring that HHAs better prepare patients and their caregiver/support person(s) (or both) to be active participants in self-care and by implementing requirements that would improve patient transitions from one care environment to another, while maintaining continuity in the patient's plan of care. We therefore propose to add § 484.58, which would require that HHAs develop and implement an effective discharge planning process that focuses on preparing patients and caregivers/support person(s) to be active partners in post-discharge care, effective transition of the patient from HHA to post-HHA care, and the reduction of factors leading to preventable readmissions.

In this proposed rule, we further address the content and timing requirements for the discharge or transfer summary for HHAs. These proposed changes incorporate the requirements of the IMPACT Act.

We are soliciting comments on the timeline for HHA implementation of the following proposed discharge planning requirements.

1. Discharge Planning Process (Proposed § 484.58(a))

We propose to establish a new standard, “Discharge planning process,” to require that the HHA’s discharge planning process ensure that the discharge goals, preferences, and needs of each patient are identified and result in the development of a discharge plan for each patient. In addition, we propose to require that the HHA discharge planning process require the regular re-evaluation of patients to identify changes that require modification of the discharge plan, in accordance with the provisions for updating the patient assessment at current § 484.55. The discharge plan must be updated, as needed, to reflect these changes.

We remind HHAs that they must continue to abide by federal civil rights laws, including Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act, and section 504 of the Rehabilitation Act of 1973, when developing a discharge planning process. To this end, HHAs should take reasonable steps to provide individuals with limited English proficiency or other communication barriers, or physical, mental, cognitive, or intellectual disabilities meaningful access to the discharge planning process, as required under Title VI of the Civil Rights Act, as implemented under 45 CFR 80.3(b)(2). Discharge planning would be of little value to patients who cannot understand or appropriately follow the discharge plans discussed in this rule. Without appropriate language assistance or auxiliary aids and services, discharge planners would not be able to fully involve the patient and caregiver/support person in the development of the discharge plan. Furthermore, the discharge planner would not be fully aware of the patient’s goals for discharge.

We propose to require that the physician responsible for the home health plan of care be involved in the ongoing process of establishing the discharge plan. We believe that physicians have an important role in the discharge planning process and we would expect that the HHA would be in communication with the physician during the discharge planning process. We also propose to require that the HHA consider the availability of caregivers/support persons for each patient, and the patient’s or caregiver’s capacity and capability to perform required care, as part of the identification of discharge needs. Furthermore, in order to incorporate patients and their families in the discharge planning process, we

propose to require that the discharge plan address the patient’s goals of care and treatment preferences.

For those patients that are transferred to another HHA or who are discharged to a SNF, IRF, or LTCH, we propose to require that the HHA assist patients and their caregivers in selecting a PAC provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. We would expect that the HHA would be available to discuss and answer patient’s and their caregiver’s questions about their post-discharge options and needs. Furthermore, the HHA must ensure that the PAC data on quality measures and data on resource use measures are relevant and applicable to the patient’s goals of care and treatment preferences.

As required by the IMPACT Act, HHAs must take into account data on quality measures and resource use measures during the discharge planning process. In order to increase patient involvement in the discharge planning process and to incorporate patient preferences, we propose that HHAs provide data on quality measures and resource use measures to the patient and caregiver that are relevant to the patient’s goals of care and treatment preferences. For example, the HHA could provide the aforementioned quality data on other PAC providers that are within the patient’s desired geographic area. HHAs should then assist patients as they choose a high quality PAC provider by discussing and answering patient’s and their caregiver’s questions about their post-discharge options and needs. We would expect that HHAs would not make decisions on PAC services on behalf of patients and their families and caregivers and instead focus on person-centered care to increase patient participation in post-discharge care decision making. Person-centered care focuses on the patient as the locus of control, supported in making their own choices and having control over their daily lives.

We propose to require that the evaluation of the patient’s discharge needs and discharge plan be documented and completed on a timely basis, based on the patient’s goals, preferences, and needs, so that appropriate arrangements are made prior to discharge or transfer. This requirement would prevent the patient’s discharge or transfer from being unduly delayed. In response to this requirement, we would expect that HHAs would establish more specific time frames for completing the evaluation and discharge plans based on

their patient’s needs and taking into consideration the patient’s acuity level and time spent in home health care. We propose to require that the evaluation be included in the clinical record. We propose that the results of the evaluation be discussed with the patient or patient’s representative. Furthermore, all relevant patient information available to or generated by the HHA itself must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the patient’s discharge or transfer.

2. Discharge or Transfer Summary Content (Proposed § 484.58(b))

We propose at § 484.58(b) to establish a new standard, “Discharge or transfer summary content,” to require that the HHA send necessary medical information to the receiving facility or health care practitioner. The information must include, at the minimum, the following:

- Demographic information, including but not limited to name, sex, date of birth, race, ethnicity, and preferred language;
 - Contact information for the physician responsible for the home health plan of care;
 - Advance directive, if applicable;
 - Course of illness/treatment;
 - Procedures;
 - Diagnoses;
 - Laboratory tests and the results of pertinent laboratory and other diagnostic testing;
 - Consultation results;
 - Functional status assessment;
 - Psychosocial assessment, including cognitive status;
 - Social supports;
 - Behavioral health issues;
 - Reconciliation of all discharge medications (both prescribed and over-the-counter);
 - All known allergies, including medication allergies;
 - Immunizations;
 - Smoking status;
 - Vital signs;
 - Unique device identifier(s) for a patient’s implantable device(s), if any;
 - Recommendations, instructions, or precautions for ongoing care, as appropriate;
 - Patient’s goals and treatment preferences;
 - The patient’s current plan of care, including goals, instructions, and the latest physician orders; and
 - Any other information necessary to ensure a safe and effective transition of care that supports the post-discharge goals for the patient.
- As part of the medication reconciliation process, we encourage

practitioners to consult with their state's PDMP. In section II.A.3 of this proposed rule, we discuss the potential benefits as well as the challenges associated with the use of PDMPs. Given these potential benefits and challenges, we are soliciting comments on whether, as part of the medication reconciliation process, practitioners should be required to consult with their state's PDMP to reconcile patient use of controlled substances as documented by the PDMP, even if the practitioner is not going to prescribe a controlled substance.

We propose to include these elements in the discharge plan so that there is a clear and comprehensive summary for effective and efficient follow-up care planning and implementation as the patient transitions from HHA services to another appropriate health care setting.

We note that many of the aforementioned proposed medical information elements required to be sent to the receiving facility or health care practitioner may not be applicable to the patient. Therefore, we would expect HHAs to include this information with a "N/A" or other appropriate notation next to each data element that does not apply to the patient. We are soliciting comments on these proposed medical information requirements.

C. Critical Access Hospital Discharge Planning

Sections 1820(e) and 1861 (mm) of the Act provide that critical access hospitals participating in Medicare and Medicaid meet certain specified requirements. We have implemented these provisions in 42 CFR part 485, subpart F, Conditions of Participation for CAHs.

Currently, there is no CAH discharge planning CoP. When CMS established requirements for the Essential Access Community Hospital (EACH) and Rural Primary Care Hospital (RPCH) providers that participated in the seven-state demonstration program in 1993, a discharge planning CoP was not developed then. Minimally, what was required under the former EACH/RPCH program was adopted for the new CAH program (see 62 FR 45966 through 46008, August 29, 1997). Currently the CoPs at § 485.631(c)(2)(ii) provide that a CAH must arrange for, or refer patients to, needed services that cannot be furnished at the CAH. CAHs are to ensure that adequate patient health records are maintained and transferred as required when patients are referred.

As previously noted, we recognize that there is significant benefit in improving the transfer and discharge requirements from an inpatient acute care facility, such as CAHs and

hospitals, to another care environment. We believe that our proposed revisions would reduce the incidence of preventable and costly readmissions, which are often due to avoidable adverse events. In addition, under the IMPACT Act, CAHs must take into account quality measures, resource use measures, and other measures to assist PAC providers, patients, and the families of patients with discharge planning, also in light of the treatment preferences of patients and the patient's goals of care. Given these concerns and the IMPACT Act mandate, we are proposing new CAH discharge planning requirements. We are soliciting comments on the timeline for implementation of the following proposed CAH discharge planning requirements.

As discussed at length in section II.A. for hospitals, we maintain that discharge planning is an important component of successful transitions from the CAH setting. Due to the availability of fewer health care resources in a rural environment, it is important to keep CAH patients on the path to recovery by ensuring that the CAH effectively communicates the discharge plan to the patient and those who will be providing support to the patient post-discharge. It is important that patients discharged to home from CAHs have the necessary support and access to the appropriate resources to assist them with recovery.

While we propose that CAHs must take into consideration the patient's preferences and goals of care during the discharge planning process, as we describe in this proposed rule, we also acknowledge that patients located in rural areas that are discharged from CAHs may have limited post-acute care options.

Facilities that offer the most appropriate post-discharge care for a particular patient's recovery needs may be located outside of the patient's community. We therefore would expect CAHs to support patients as they choose an appropriate PAC setting that meets their preferences and goals of care, while informing the patient of the benefits of selecting the most appropriate setting for their post-discharge needs, even if the facility is outside of the patient's desired location.

Consistent communication between health care providers in all patient care settings would assist in better patient placement. However, this level of communication has not been consistently achieved among the numerous healthcare providers within communities across the country. Therefore, we believe that it is vital that

rural providers collaborate with each other to optimize the use of post-discharge providers in rural areas.

We propose to develop requirements in the form of five standards at § 485.642. We would require that all inpatients and certain categories of outpatients be evaluated for their discharge needs and that the CAH develop a discharge plan. We also propose to require that the CAH provide specific discharge instructions, as appropriate, for all patients.

We propose that each CAH's discharge planning process must ensure that the discharge needs of each patient are identified and must result in the development of an appropriate discharge plan for each patient.

We remind CAHs that they must continue to abide by federal civil rights laws, including Title VI of the Civil Rights Act of 1964, the Americans with Disabilities Act, and section 504 of the Rehabilitation Act of 1973, when developing a discharge planning process. To this end, CAHs should take reasonable steps to provide individuals with limited English proficiency or physical, mental, cognitive, and intellectual disabilities meaningful access to the discharge planning process, as required under Title VI of the Civil Rights Act, as implemented at 45 CFR § 80.3(b)(2). Discharge planning would be of little value to patients who cannot understand or appropriately follow the discharge plans discussed in this rule. Without appropriate language assistance or auxiliary aids and services, discharge planners would not be able to fully involve the patient and caregiver/support person in the development of the discharge plan. Furthermore, the discharge planner would not be fully aware of the patient's goals for discharge.

Additionally, effective discharge planning will assist CAHs in accordance with the U.S. Supreme Court's holding in *Olmstead vs. L.C.*, which found that the unjustified segregation of people with disabilities is a form of unlawful discrimination under the ADA. We note that effective discharge planning may assist CAHs in ensuring that individuals being discharged, who would otherwise be entitled to institutional services, have access to community based services when: (a) such placement is appropriate; (b) the affected person does not oppose such treatment; and (c) the placement can be reasonably accommodated.

1. Design (Proposed § 485.642(a))

We propose at § 485.642(a) to establish a new standard, "Design," to require a CAH to have policies and

procedures that are developed with input from the CAH's professional healthcare staff, nursing leadership as well as other relevant departments. The policies and procedures must be approved by the governing body or responsible individual and be specified in writing (see proposed § 482.43).

2. Applicability (Proposed § 485.642(b))

We propose at § 485.642(b) to establish a new standard, "Applicability", to require the CAH's discharge planning process to identify the discharge needs of each patient and to develop an appropriate discharge plan. We note that, in accordance with section 1814(a)(8) of the Act and § 424.15, physicians must certify that the individual may reasonably be expected to be discharged or transferred to a hospital within 96 hours after admission to the CAH. We propose to require that the discharge planning process must apply to all inpatients, observation patients, patients undergoing surgery or same-day procedures where anesthesia or moderate sedation was used, emergency department patients identified as needing a discharge plan, and any other category of patients as recommended by the professional healthcare staff and approved by the governing body or responsible individual.

3. Discharge Planning Process (Proposed § 485.642(c))

We propose at § 485.642(c), "Discharge planning process," to require that CAHs implement a discharge planning process to begin identifying the anticipated post-discharge goals, preferences, and discharge needs of the patient and begin to develop an appropriate discharge plan for the patients identified in proposed § 485.642(b). We propose at § 485.642(c)(1) to require that a registered nurse, social worker, or other personnel qualified in accordance with the CAH's discharge planning policies must coordinate the discharge needs evaluation and development of the discharge plan. We also propose at § 485.642(c)(2) to require that the discharge planning process begin within 24 hours after admission or registration for each applicable patient identified under the proposed requirement at § 485.642(b), and is completed prior to discharge home or transfer to another facility, without unduly delaying the patient's discharge or transfer. If the patient's stay was less than 24 hours, the discharge needs would be identified prior to the patient's discharge home or transfer to another facility and without unnecessarily delaying the patient's

discharge or transfer. We note that this policy does not pertain to emergency-level transfers for patients who require a higher level of care. However, while an emergency-level transfer would not need a discharge evaluation and plan, we would expect that the CAH would send necessary and pertinent information with the patient that is being transferred to another facility.

We propose at § 485.642(c)(3) that the CAH's discharge planning process must require regular reevaluation of patients to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed to reflect these changes. We propose at § 485.642(c)(4) that the practitioner responsible for the care of the patient must be involved in the ongoing process of establishing the discharge plan.

We propose at § 485.642(c)(5) that the CAH would be required to consider caregiver/support person availability and community based care, and the patient's or caregiver's/support person's capability to perform required care including self-care, follow-up care from a community based provider, care from a support person(s), care from and being discharged back to community-based health care providers and suppliers, or, in the case of a patient admitted from a long term care or other residential facility, care in that setting, as part of the identification of discharge needs. We also propose to require that CAHs must consider the availability of and access to non-health care services for patients, which may include home and physical environment modifications, transportation services, meal services, or household services, including housing for homeless patients. In addition, we encourage CAHs to consider the availability of supportive housing, as an alternative to homeless shelters that can facilitate continuity of care for patients in need of housing.

As part of the on-going discharge planning process, we propose in § 485.642(c)(5) that CAHs would need to identify areas where the patient or caregiver/support person(s) would need assistance and address those needs in the discharge plan. CAHs must consider the following in evaluating a patient's discharge needs including but not limited to:

- Admitting diagnosis or reason for registration;
- Relevant co-morbidities and past medical and surgical history;
- Anticipated ongoing care needs post-discharge;
- Readmission risk;
- Relevant psychosocial history;

- Communication needs, including language barriers, diminished eyesight and hearing, and self-reported literacy of the patient, patient's representative or caregiver/support person(s), as applicable;

- Patient's access to non-health care services; and community-based care providers; and

- Patient's goals and preferences.

We refer readers to Section II. A. 3 for a more detailed explanation of our expectations for this requirement and for additional resources.

During the evaluation of a patient's relevant co-morbidities and past medical and surgical history, we encourage practitioners to consult with their state's PDMP. In section II.A.3 of this proposed rule, we discuss the potential benefits as well as the challenges associated with the use of PDMPs. Given these potential benefits and challenges, we are soliciting comments on whether practitioners should be required to consult with their state's PDMP and review a patient's risk of non-medical use of controlled substances and substance use disorders as indicated by the PDMP report.

We propose at § 485.642 (c)(6) that the patient and caregiver/support person(s) would be involved in the development of the discharge plan, and informed of the final plan to prepare them for their post-CAH care.

We propose at § 485.642 (c)(7) to require that the patient's discharge plan address the patient's goals of care and treatment preferences. During the discharge planning process, we would expect that the appropriate staff would discuss the patient's post-acute care goals and treatment preferences with the patient, the patient's family or the caregiver (or both) and subsequently document these goals and preferences in the discharge plan. These goals and treatment preferences should be taken into account throughout the entire discharge planning process.

We propose at § 485.642(c)(8) to require that CAHs assist patients, their families, or their caregiver's/support persons in selecting a PAC provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH, data on quality measures and data on resource use measures. We would expect that the CAH would be available to discuss and answer patients and their caregiver's questions about their post-discharge options and needs. We would also expect the CAH to document in the medical record that the quality measures and resource use measures were shared with the patient and used to assist the patient during the discharge planning process.

Furthermore, the CAH would have to ensure that the PAC data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

As required by the IMPACT Act, CAHs would have to take into account data on quality measures and data on resource use measures during the discharge planning process. In order to increase patient involvement in the discharge planning process and to emphasize patient preferences throughout the patient's course of treatment, CAHs should tailor the data on PAC provider quality measures and resource use measures to the patient's goals of care and treatment preferences. For example, the CAH could provide the aforementioned quality data on PAC providers that are within the patient's desired geographic area. In another instance, CAHs could provide quality data on HHAs based on the patient's preference to continue their care upon discharge to home. CAHs should assist patients as they choose a high quality PAC provider. However, we would expect that CAHs would not make decisions on PAC services on behalf of patients and their families and caregivers and instead focus on person-centered care to increase patient participation in post-discharge care decision making. Person-centered care focuses on the patient as the locus of control, supported in making their own choices and having control over their daily lives.

We propose at § 485.642(c)(9) to require that the evaluation of the patient's discharge needs and discharge plan would have to be documented and completed on a timely basis, based on the patient's goals, preferences, strengths, and needs. This will ensure that appropriate arrangements for post-CAH care are made before discharge. We believe that the CAH would establish more specific time frames for completing the evaluation and discharge plans based on the needs of their patients and their own operations. We propose to require that the evaluation be included in the medical record. The results of the evaluation must be discussed with the patient or patient's representative. All relevant patient information would have to be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the patient's discharge or transfer.

We also propose at § 485.642(c)(10) to require that the CAH assess its discharge planning process in accordance with the existing requirements at § 485.635(a)(4). The assessment must include ongoing,

periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission to ensure that they are responsive to patient discharge needs.

4. Discharge to Home (Proposed § 485.642(d)(1) through (3))

We propose at § 485.642(d)(1) to establish a new standard, "Discharge to home", to require that discharge instructions be provided at the time of discharge to the patient, or the patient's caregiver/support person (or both). Also, if the patient is referred to a PAC provider or supplier, the discharge instructions must be provided to the PAC provider/supplier. Instruction on post-discharge care must include, but are not limited to, instruction on post-discharge care to be used by the patient or the caregiver/support person(s) in the patient's home, as identified in the discharge plan. We also propose at § 485.642(d)(2) to require that the instructions must include:

- Instruction on post-discharge care to be used by the patient or the caregiver/support person(s) in the patient's home, as identified in the discharge plan;
- Written information on warning signs and symptoms that may indicate the need to seek immediate medical attention;
- Prescriptions for medications that are required after discharge, including the name, indication, and dosage of each drug along with any significant risks and side effects of each drug as appropriate to the patient;
- Reconciliation of all discharge medications with the patient's pre-hospital admission/registration medications (both prescribed and over-the-counter); and
- Written instructions regarding the patient's follow-up care, appointments, pending or planned diagnostic tests (or both), and pertinent contact information, including telephone numbers for practitioners involved in follow-up care.

As part of the medication reconciliation process, we encourage practitioners to consult with their state's PDMP. In section II.A.3 of this proposed rule, we discuss the potential benefits as well as the challenges associated with the use of PDMPs. Given these potential benefits and challenges, we are soliciting comments on whether, as part of the medication reconciliation process, practitioners should be required to consult with their state's PDMP to reconcile patient use of controlled substances as documented by the PDMP, even if the practitioner is not

going to prescribe a controlled substance.

In addition to the patient receiving discharge instructions, it is important that the providers responsible for follow-up care with a patient (including the PCP or other practitioner) receive the necessary medical information to support continuity of care. We therefore propose at § 485.642(d)(3) to require that the CAH send the following information to the practitioner(s) responsible for follow up care, if the practitioner is known to the hospital and has been clearly identified:

- A copy of the discharge instructions and the discharge summary within 48 hours of the patient's discharge;
- Pending test results within 24 hours of their availability;
- All other necessary information as specified in proposed § 485.642(e)(2).

We remind CAHs to provide this information in a manner that complies with all applicable privacy and security regulations. We would expect that discharge instructions would be carefully designed and written in plain language and designed to be easily understood by the patient or the patient's caregiver/support person (or both). In addition, as a best practice, CAHs should confirm patient or the patient's caregiver/support person (or both) understanding of the discharge instructions. We recommend that CAHs consider the use of "teach-back" during discharge planning and upon providing discharge instructions to the patient. We refer readers to Section II. A. 3 for more resources on the "teach-back" method.

We propose at § 485.642(d)(4) to require CAHs to establish a post-discharge follow-up process. We believe that post-discharge follow-up can help ensure that patients comprehend and adhere to their discharge instruction and medication regimens and improve patient safety and satisfaction. We are proposing that CAHs have the flexibility to determine the appropriate time and mechanism of the follow up process to meet the needs of their patients. However, we note the importance of ensuring that CAHs follow-up, post-discharge, with their most vulnerable patients, including those with behavioral health conditions.

5. Transfer of Patients to Another Health Care Facility (Proposed § 485.642(e))

When a patient is transferred to another facility, that is another CAH, hospital, or a PAC provider, we propose at § 485.642(e) to require that the CAH send necessary medical information to the receiving facility at the time of transfer. The necessary medical information must include:

- Demographic information, including but not limited to name, sex, date of birth, race, ethnicity, and preferred language;
- Contact information for the practitioner responsible for the care of the patient as described at paragraph (b)(4) of this section and the patient's caregiver/support person(s);
- Advance directive, if applicable;
- Course of illness/treatment;
- Procedures;
- Diagnoses;
- Laboratory tests and the results of pertinent laboratory and other diagnostic testing;
- Consultation results;
- Functional status assessment;
- Psychosocial assessment, including cognitive status;
- Social supports;
- Behavioral health issues;
- Reconciliation of all discharge medications with the patient's pre-hospital admission/registration medications (both prescribed and over-the-counter);
- All known allergies; including medication allergies;
- Immunizations;
- Smoking status;
- Vital signs;
- Unique device identifier(s) for a patient's implantable device (s), if any;
- All special instructions or precautions for ongoing care; as appropriate;
- Patient's goals and treatment preferences; and
- Any other necessary information including a copy of the patient's discharge instructions, the discharge summary, and any other documentation as applicable, to ensure a safe and effective transition of care that supports the post-discharge goals for the patients.

We have discussed the rationale for these provisions in our discussion of the hospital provisions in section II.A. We are soliciting comments on these proposed medical information requirements.

III. Collection of Information Requirements

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

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

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

A. ICRs Regarding Hospital Discharge Planning (§ 482.43)

Proposed § 482.43(b) would require that the discharge process applies to all inpatients and to all outpatients identified at § 482.43(b)(2) through (5). The current hospital CoPs at § 482.43(a) require hospitals to have a discharge planning process for patients that have been identified as likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning and for patients who have discharge planning requested by themselves, someone else who is acting on their behalf, or their physician for actual discharge planning. Thus, since hospitals would shift from evaluating patients for potential discharge planning to actually providing a discharge plan for the vast majority of patients, hospitals would have to revise their policies and procedures to comply with the proposed requirements in this section.

It should be noted here that the proposed requirements at § 482.43(c)(8) and § 482.43(c)(9) (and all similar proposed requirements set out at proposed § 485.642(c)(8) and (9) for CAHs and § 484.58(a)(6) and (7) for HHAs), which correspond to the requirements of the IMPACT Act, are exempted from the application of the PRA pursuant to section 1899B(m). Therefore, we are not required to estimate the public reporting burden for information collection requirements for these specific elements of the proposed rule in accordance with chapter 35 of title 44, United States Code. Nor are we required to undergo the specific public notice requirements of the PRA. Therefore, the estimates we provide in the Regulatory Impact Analysis (RIA) section of this proposed rule are essentially identical to those we would estimate under the PRA with respect to the elements set out in section 1899B of the Act. The public comment period on the proposed rule will give those affected an equivalent opportunity with

the greater procedural benefits of the Administrative Procedure Act and Executive Order 12866. The exemption created by the IMPACT Act does not exempt the entirety of this proposed rule from PRA analysis. We further note that these proposed rules deal with the transmission of data on quality measures and data on resource use measures to patients that, are provided by the government to health care providers, not with the costs associated with its preparation. This rule does not deal with those costs.

Proposed § 482.43(d) would require hospitals to provide to all patients discharged to home, with or without a referral to a community-based service provider, discharge instructions that must include, at a minimum, those items identified in § 482.43(d)(2)(i) through (v). The current hospital CoPs do not contain any requirements for written discharge instructions under that heading. However, there are requirements for hospitals to provide certain information to patients. There is a requirement that "the patient and family members or interested persons must be counseled to prepare them for post-hospital care" (§ 482.43(c)(5)). When a hospital transfers or refers a patient, they must send the necessary medical information to the appropriate facility or outpatient service, as needed, for follow-up or ancillary care (§ 482.43(d)). When appropriate, there are requirements to provide lists of available providers, such as home health providers, to patients (§ 482.43(c)(6)). Thus, hospitals are already providing counseling to patients, their families, or other interested parties and are providing certain written information.

Whenever a patient is discharged or transferred to another facility, proposed § 482.43(e) would require hospitals to send necessary medical information to the receiving facility at the time of transfer. The necessary information that the hospital must send to the receiving facility includes all the items listed at proposed § 482.43(e)(2)(i) through (viii). The current hospital CoPs already require hospitals to send along with any patient that is transferred or referred to another facility the necessary medical information for the patient's follow-up or ancillary care to the appropriate facility (§ 482.43(d)). Overall, we believe that almost all of the proposed changes for hospitals constitute a clarification and restatement of the current requirements along with their interpretive guidelines, or simply state as requirements practices that most hospitals already follow for most patients. For example, we believe that

medication reconciliation is a near universal practice for inpatients. Thus, we believe that hospitals are already following most of these proposed requirements and therefore we will not be assessing any additional burden for this section beyond our estimates of the one-time cost to hospitals to modify their policies and procedures in order to ensure that they are meeting the requirements of this proposed rule. There are, however, some proposed requirements that expand beyond current practice, or that fewer hospitals currently follow. These proposed requirements included:

- Discharge plans for certain categories of outpatients, including, but not limited to patients receiving observation services, patients who are undergoing surgery or other same-day procedures where anesthesia or moderate sedation is used, emergency department patients who have been identified by a practitioner as needing a discharge plan, and any other category of outpatient as recommended by the medical staff, approved by the governing body and specified in the hospital's discharge planning policies and procedures; and

- The practitioner responsible for the care of the patient must be involved in the ongoing process of establishing the patient's goals of care and treatment preferences that inform the discharge plan, just as they are with other aspects of patient care during the hospitalization or outpatient visit.

In the estimates that follow in this section of the preamble and in the RIA, we estimate hourly costs. Using data from the Bureau of Labor Statistics, we have estimates of the national average hourly wage for all medical professions (for an explanation of these data see http://www.bls.gov/news.release/archives/ocwage_03252015.htm). These data do not include the employer share of fringe benefits such as health insurance and retirement plans, the employer share of OASDI taxes, or the overhead costs to employers for rent, utilities, electronic equipment, furniture, human resources staff, and other expenses that are incurred for employment. The HHS-wide practice is to account for all such costs by adding 100 percent to the hourly cost rate, doubling it for purposes of estimating the costs of regulations.

With respect to the one-time costs of reviewing the newly stated requirements and of reviewing and in some cases modifying existing procedures to come into compliance, we estimate that this would require a physician, a registered nurse, and an administrator using the average hourly

salaries as estimated in this proposed rule. We estimate that each person would spend 8 hours on this activity for a total of 24 hours per hospital at a cost of \$3,424 ((8 hours × \$67 for a registered nurse's hourly salary) + (8 hours × \$174 for hospital CEO/administrator's hourly salary) + (8 hours × \$187 for a physician's hourly salary)). The total burden hours are 117,600 (24 hours × 4,900 hospitals). For all hospitals to comply with this requirement, we estimate a total one-time cost of approximately \$17 million (4,900 hospitals × \$3,424). These time estimates are based on our best estimates of the time needed, on average, to review the final rule, compare its provisions with current practice at the hospital, and determine what changes would be needed and what instructions would need to be issued. For some hospitals, less time would be needed, and for some hospitals more, depending on current practices. These estimates are based on the judgments of CMS staff involved in the Survey and Certification process. We are unaware of any "time and motion" or similar studies that would provide a quantitative and reliable source for such estimates. We welcome comments and data that would help us improve the estimates.

For the requirements that exceed current practice or that are not universally followed, we use the following cost assumptions, based on the following hourly salaries: physician at \$187; registered nurse at \$67; Advanced Practice Registered Nurse (APRN) at \$94; Physicians Assistant (PA) at \$94; and healthcare social worker at \$52. We would expect a registered nurse and healthcare social worker to carry out the duties of evaluating and planning for a patient's discharge while we would expect a physician, APRN, or PA to fulfill the practitioner involvement in the discharge plan requirement.

For the estimated cost of hospitals to provide additional discharge plans for the proposed new categories of outpatients, we started with the most recent data from the CDC on hospital outpatient and emergency department (ED) visits that showed approximately 126 million visits and 118 million visits (not including the 18.3 million emergency department visits that resulted in inpatient admissions), respectively, in 2011 (<http://www.cdc.gov/nchs/fastats/hospital.htm>). We believe that only 5 percent of hospital outpatient visits, or approximately 6 million visits, and 5 percent of ED visits, or approximately 6 million visits, would need a discharge

plan. We base this belief on our experience with hospitals that shows that most outpatient visits, similar to a physician's office visit, do not need a discharge plan of any type and that most ED visits already receive some type of discharge plan.

Also according to the CDC, of the 34.7 million ambulatory surgery visits in 2006, 19.9 million occurred in hospitals (<http://www.cdc.gov/nchs/data/nhsr/nhsr011.pdf>). For the purposes of this analysis, we believe that approximately 95 percent of patients who undergo hospital ambulatory surgeries would already receive discharge plans and are thus not included in our cost estimates. Therefore, we believe that 5 percent, or 1 million, of these patients do not currently receive discharge plans and are included in our cost estimates here.

We also have reason to believe that approximately 2 million outpatients receive observation care annually (<http://khn.org/news/observation-care-faq/>) and that all but 5 percent, or 100,000 outpatients, currently receive a discharge plan. This would then bring our estimate of additional discharge plans annually to approximately 13 million patients.

Using the number of 13 million outpatients, we estimate the amount of time that these discharge plans would take hospitals to develop and provide, including the cost of the additional proposed requirements previously noted in this proposed rule, that is, practitioner involvement in the development of the discharge plan. We believe that these additional requirements are already being performed for inpatients discharged, so we have not estimated any additional cost for these patients.

We believe that hospital APRNs and PAs would spend equal time as physicians, RNs, and healthcare social workers on discharge planning (5 minutes or 0.083 hours) on an equal number of outpatients. We averaged the salaries (\$94 + \$94 + \$187 + \$67 + \$52)/5 = \$99 per hour)). Thus, we estimate that complying with the proposed requirements of new outpatient discharge plans and practitioner involvement in those plans would cost approximately \$107 million annually (13 million patients × 0.083 hours × \$99 average hourly wage for APRNs, PAs, MDs/Doctors of Osteopathic Medicine (DOs), RNs, and healthcare social workers).

These estimates are based on the judgment of CMS staff as well as our experience with hospitals, both as CMS staff and as active hospital staff members. We welcome data and comments on these estimates.

B. ICRs Regarding Home Health Discharge Planning (§ 484.58)

We propose a new CoP at § 484.58 that would require HHAs to develop and implement an effective discharge planning process that focuses on preparing patients to be active partners in post-discharge care, effective transition of the patient from HHA to post-HHA care, and the reduction of factors leading to preventable readmissions.

We propose to establish a new standard at § 484.58(a), "Discharge planning process," to require that the HHA's discharge planning process ensure that the discharge needs of each patient are identified and result in the development of a discharge plan for each patient. In addition, we propose to require that the HHA discharge planning process require the regular re-evaluation of patients to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

We propose to require that the physician responsible for the home health plan of care be involved in the ongoing process of establishing the discharge plan. We would expect that the HHA would be in communication with the physician during the discharge planning process. We also propose to require that as part of identifying the patient's discharge needs, the HHA consider the availability of caregivers/support persons for each patient whether through self-care, care from a support person(s), care from community-based health care providers and agencies, or care from a long-term care facility or other residential facility as part of the identification of discharge needs. The proposed requirement would also require the HHA to consider the patient's or caregiver's capacity and capability to provide the necessary care. Furthermore, in order to incorporate patients and their families in the discharge planning process, we propose to require that the discharge plan address the patient's goals of care and treatment preferences.

We propose to require that the evaluation of the patient's discharge needs and discharge plan must be documented, completed on a timely basis and be based on the patient's needs to ensure that the patient's discharge or transfer is not unduly delayed. We believe that HHAs would establish more specific time frames for completing the evaluation and discharge plans based on the needs of their patients and their own operations. We propose to require that the evaluation be

included in the medical record. We propose that the results of the evaluation be discussed with the patient or patient's representative. Furthermore, all relevant patient information available to or generated by the HHA itself must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the patient's discharge or transfer.

We base our HHA burden cost estimates on those discussed previously in this proposed rule for hospitals and CAHs with the relevant modifications for HHAs. First, HHAs would need to review their current policies and procedures and update them so that they comply with the requirements in proposed § 484.58(a). This would be a one-time burden on the HHA. We estimate that this would require a physician, a registered nurse, and an administrator using the average hourly salaries as estimated in this proposed rule. Note that we are estimating a lower average hourly salary for an HHA administrator than that previously estimated for a hospital CEO/administrator. We estimate that each person would spend 8 hours on this activity for a total of 24 hours per HHA at a cost of \$2,816 ((8 hours × \$67 for a RN's hourly salary) + (8 hours × \$98 for an administrator's hourly salary) + (8 hours × \$187 for a physician's hourly salary)). For all HHAs to comply with this requirement, we estimate a total one-time cost of approximately \$34 million (11,930 HHAs × \$2,816).

Furthermore, we believe that for a HHA to comply with the proposed provisions for this new standard the combined services of a physician, a registered nurse, and a social worker would be required. We use the following average hourly costs for a physician, a registered nurse, and a social worker respectively: \$187, \$67, and \$52. We will also estimate the annual burden cost by analyzing the two new proposed standards as a combined burden in this proposed rule.

We propose at § 484.58(b) to establish another new standard, "Discharge or transfer summary content," to require that the HHA send necessary medical information to the receiving facility or practitioner. The information must include:

- Demographic information, including but not limited to name, sex, date of birth, race, ethnicity, preferred language;
- Contact information for the physician responsible for the home health plan of care;
- Advance directive, if applicable;
- Course of illness/treatment;

- Procedures;
- Diagnoses;
- Laboratory tests and the results of pertinent laboratory and other diagnostic testing;
- Consultation results;
- Functional status assessment;
- Psychosocial assessment, including cognitive status;
- Social supports;
- Behavioral health issues;
- Reconciliation of all discharge medications (both prescribed and over-the-counter);
- All known allergies, including medication allergies;
- Immunizations;
- Smoking status;
- Vital signs;
- Unique device identifier(s) for a patient's implantable device(s), if any;
- Recommendations, instructions, or precautions for ongoing care, as appropriate;
- Patient's goals of care and treatment preferences;
- The patient's current plan of care, including goals, instructions, and the latest physician orders; and
- Any other information necessary to ensure a safe and effective transition of care that supports the post-discharge goals for the patient.

We propose to include these elements in the discharge plan to provide the clear and comprehensive summary that is necessary for effective and efficient follow-up care planning and implementation as the patient transitions from HHA services to another appropriate health care setting.

To meet these two new proposed standards, it would take an HHA approximately 10 minutes (0.17 hours) per patient. Of that 10 minutes, 2 minutes (0.033 hours) would be covered by the physician, 3 minutes (0.05 hours) by the social worker, and the remaining 5 minutes (0.083 hours) by the RN. Thus, for the 11,930 HHAs, we estimate that complying with this requirement would require 594,000 burden hours (18 million patients × 0.033 hours) for physicians at an approximate cost of \$111 million (594,000 burden hours × \$187 average hourly salary); 900,000 burden hours (18 million patients × 0.05 hours) for social workers at an approximate cost of \$47 million (900,000 burden hours × \$52); and 1.5 million burden hours (18 million patients × 0.083 hours) for RNs at an approximate cost of \$101 million (1.5 million burden hours × \$67). The total annual cost for all HHAs would be approximately \$259 million or \$21,710 per HHA (\$259,000,000/11,930 HHAs).

We also estimate that a HHA would spend 2.5 minutes per patient sending

the discharge summary to the patient's next source of healthcare services, for a total of 62 hours per average HHA annually ((2.5 minutes per patient × 1,488 patients)/60 minutes per hour) at a cost of \$1,984 for an office employee to send the required documentation (\$32 per hour × 62 hours). Complying with this provision would require an estimated 739,660 hours (62 hours per HHA × 11,930 HHAs) and \$24 million (\$1,984 per HHA × 11,930 HHAs) for all HHAs annually.

Thus, we estimate compliance with this new CoP would cost HHAs a one-time cost of \$34 million and approximately \$283 million annually.

As previously indicated, these estimates are based on estimates for hospitals and CAHs with the relevant modifications for HHAs. We welcome data and comments on these estimates.

C. ICRs Regarding Critical Access Hospital Discharge Planning (§ 485.642)

Currently, the CoPs at § 485.631(c)(2)(ii) provide that a CAH must arrange for, or refer patients to, needed services that cannot be furnished at the CAH. CAHs are to ensure that adequate patient health records are maintained and transferred as required when patients are referred.

As previously noted, we recognize that there is significant benefit in improving the transfer and discharge requirements from an inpatient acute care facility, such as CAHs and hospitals, to another care environment. We believe that our proposed revisions would reduce the incidence of preventable and costly readmissions, which are often due to avoidable adverse events. In addition, the IMPACT Act requires that hospitals and CAHs take into account quality, resource use data, and other data to assist PAC providers, patients, and the families of patients with discharge planning, while also addressing the treatment preferences of patients and the patient's goals of care. In light of these concerns and the requirements of the IMPACT Act, we are proposing new CAH discharge planning requirements.

We propose to develop requirements in the form of new CoPs with five standards at § 485.642. We would require that all patients be evaluated for their discharge needs and that the CAH develop a discharge plan. We also propose to require that the CAH provide specific discharge instructions, as appropriate, for all patients.

We also propose that each CAH's discharge planning process must ensure that the discharge needs of each patient are identified and must result in the development of an appropriate

discharge plan for each patient. The current CAH CoP at § 485.635(d)(4) requires the CAH to develop a nursing care plan for each inpatient. The Interpretive Guidelines for § 485.635(d)(4) state that the plan includes planning the patient's care while in the CAH as well as planning for transfer to a hospital or a PAC facility or for discharge. Because the proposed CAH discharge planning requirements mirror those proposed for hospitals, we believe that CAHs, like hospitals, are essentially already performing many of the proposed requirements and estimate the burden to be minimal. We are assessing burden only for those areas that we believe that CAHs are not already doing under the current requirements of the nursing care plan at § 485.635(d)(4).

For proposed § 485.642(b), CAHs would need to shift from evaluating patients for potential discharge planning to actually doing discharge planning for the vast majority of patients. CAHs would have to revise their policies and procedures to comply with the proposed requirements in this section. First, CAHs would need to review their current policies and procedures and update them so that they comply with the requirements in proposed § 485.642(b). This would be a one-time burden on the CAH. We estimate that this would require a physician, a registered nurse, and an administrator using the average hourly salaries as estimated in this proposed rule. Note that we are estimating a lower average hourly salary for a CAH administrator than that previously estimated for a hospital CEO/administrator. We estimate that each person would spend 16 hours on this activity for a total of 48 hours per CAH at a cost of \$5,632 ((16 hours × \$67 for a registered nurse's hourly salary) + (16 hours × \$98 for an administrator's hourly salary) + (16 hours × \$187 for a physician's hourly salary)). For all CAHs to comply with this requirement, we estimate a total one-time cost of approximately \$7.5 million (1,328 CAHs × \$5,632).

Similar to the proposed hospital requirements at § 482.43(c), proposed § 485.642(c) would require the CAH to implement a discharge planning process that identifies, within 24 hours after admission or registration in the CAH, the anticipated discharge needs for the patients identified under the proposed requirement at § 485.642(b), along with several provisions supporting the requirement proposed here.

Proposed § 485.642(c) would require that the CAH's discharge planning process promote early identification of the anticipated discharge needs of each

patient, and development of an appropriate discharge plan for each patient for whom a discharge plan is applicable in accordance with proposed § 485.642(b). The identification of the patient's needs and the development of the discharge plan must comply with all of the requirements in § 485.642(c)(1) through (9). Proposed § 485.642(c)(4) specifically would require that "The licensed practitioner responsible for the care of the patient must be involved in the ongoing process of establishing the discharge plan." The current CAH CoPs do not contain any similar requirement.

The burden associated with the requirement that a practitioner responsible for the patient's care be involved with the patient's discharge would include the time needed for a practitioner to assist in establishing the discharge plan. We believe that practitioner involvement in the establishing of the discharge plan would constitute a usual and customary business practice as defined in the implementing regulations of the PRA at 5 CFR 320.3(b)(2) and that CAHs are already doing this. The majority of CAHs that are deemed for participation in Medicare are accredited by The Joint Commission, which requires a CAH to have "the patient, the patient's family, *licensed independent practitioners, physicians, clinical psychologists, and staff involved in the patient's care, treatment, and services* [emphasis added] participate in planning the patient's discharge or transfer." Such practitioner involvement (where indicated and where feasible) is in our view an essential part of patient care and one that we expect CAH staff carefully follow wherever possible. Therefore, we will not be assessing any burden for this activity.

We believe that practitioners already are communicating with the staff that are caring for their patients and that the practitioner's involvement in the establishment of the discharge plan would occur during those usual interactions with the staff. We also expect that practitioners would review the discharge plan in conjunction with their review of the patient's CAH medical record. The practitioner would write the order to discharge the patient, as well as any prescriptions for medications and other orders for the patient. However, the proposed requirement envisions a more direct involvement in the ongoing process of establishing a discharge plan. Thus, we believe that practitioners would spend more time discussing the discharge plan with nurses and other CAH personnel.

The additional time the practitioner would be required to spend on

discharge planning would vary greatly in accordance with the patient's need for care, treatment, and services after he or she was discharged from the CAH. Practitioners must already be involved in many circumstances because they must order or authorize certain post-discharge care. In addition, there is no need for a practitioner to spend additional time on discharge planning for patients who only require prescriptions for medications and an order to follow-up with their primary care provider or those who pass away while hospitalized. We use the following average hourly costs for a physician, an advanced practice registered nurse, and a physician assistant respectively: \$187, \$94, and \$94. We believe that CAH APRNs and PAs would spend more time than physicians on discharge planning (5 minutes versus 2 minutes or 0.083 hours versus 0.033 hours). We estimate these practitioners would spend more time (approximately 0.083 hours per patient) on discharge planning for approximately 20 percent of CAH patients or approximately 120,000 patients. We estimate physicians would spend approximately 0.033 burden hours on 5 percent of CAH patients or approximately 30,000 patients. Thus, we estimate that complying with the requirements in this section would cost \$1.1 million annually ((120,000 patients \times 0.083 hours \times \$94 average hourly wage for APRNs and PAs) + (30,000 patients \times 0.033 hours \times \$187 average hourly wage for physicians)).

For proposed § 485.642(d), CAHs would be required to provide to all patients discharged to home, with or without a referral to a community-based service provider, discharge instructions that must include, at a minimum, those items identified in § 485.642(d)(2)(i) through (v). The current CAH CoPs do not contain any requirements for written discharge instructions.

The burden from the requirement to include discharge instructions in the discharge plan and document those instructions is the resources needed to develop the discharge plan and instructions. Based on our experience with the 1,328 CAHs, we believe they are already doing some form of discharge planning and providing discharge instructions for most of their patients. However, we do not believe

they are providing this care for all of their patients. Of the approximately 600,000 patients discharged from CAHs each year, we estimate that about 60,000 additional patients would require discharge planning to comply with the requirement in this section. A nurse would probably perform this activity at an hourly salary of \$67. This activity should require 30 minutes or 0.5 hours. Thus, for the 1,328 CAHs, we estimate that complying with this requirement would require 30,000 burden hours (60,000 patients \times 0.5 hours) at a cost of \$2 million (30,000 \times \$67 hourly nurse's salary). Approximately 5 minutes of this time would be spent consulting with either the MD/DO or the APRN/PA at a cost of \$702,180 (60,000 patients \times 0.083 hours \times \$141 (((\$187 + \$94)/2)), resulting in an approximate total of \$2.7 million annually.

Whenever a patient is discharged or transferred to another facility, proposed § 485.642(e) would require CAHs to send necessary medical information to the receiving facility at the time of transfer. The necessary information that the CAH must send to the receiving facility includes all the items listed at proposed § 485.642(e)(2)(i) through (viii). Currently, the CoPs at § 485.631(c)(2)(ii) provide that a CAH must arrange for, or refer patients to, needed services that cannot be furnished at the CAH. CAHs are to ensure that adequate patient medical records are maintained and transferred as required when patients are referred. We believe that CAHs are already providing the information listed at proposed § 485.642(d)(2)(i) through (viii), except for (ii), which specifically requires an assessment of functional status, and (iv), which requires the reconciliation of all discharge medications with the patient's pre-CAH admission/registration medications (both prescribed and over-the-counter), including known allergies. Although we believe all CAHs are ensuring that information about functional status and about known allergies is being forwarded, we are not certain that they are all reconciling the pre-CAH medications with the discharge medications. Therefore, we will analyze a burden for this reconciliation. Since both proposed § 485.642(d)(2)(iv) and § 482.642(e)(2)(iv) require medication reconciliation, we will assess the

burden for both of these subsections together.

The burden for reconciling pre-admission/registration medications (both prescribed and over-the-counter) with the discharge medications would be the resources required to review the patient's chart to identify all of a patient's pre-admission medications and compare them to the discharge medications. Typically, a physician, nurse, or other healthcare provider would do a history for each patient upon admission. A nurse would usually then compare the medications the patient was taking pre-admission to those ordered by the practitioner and reconcile them. If there were any discrepancies that the nurse questioned, he or she would then consult with the practitioner caring for the patient. When a patient is ready for discharge, the nurse would then compare the pre-admission medications with the discharge medications. If he or she questioned any changes, the nurse would need to question the prescribing practitioner about the discrepancy.

Based on our experience with CAHs, we believe that a nurse would review the patient's chart and reconcile the pre-admission and discharge medications. The time required for this reconciliation would vary greatly depending upon the number of medications a patient was taking, both pre-admission and at discharge, and the number of changes or discrepancies that the nurse questioned. We estimate that this activity would require an average of 3 minutes for each patient or 0.05 hours. We estimate that there are about 600,000 discharges annually that would require this medication reconciliation. Nurses earn an average hourly salary of \$67. Thus, complying with this requirement would require an estimated 30,000 burden hours (600,000 discharges \times 0.05 hours per patient) across all CAHs annually at a cost of \$2 million (30,000 burden hours \times \$67).

We welcome comments on these estimates and any available data that we could use to improve our estimates. Based on the previously stated estimates, to comply with all of the requirements in proposed § 485.642, we estimate a total one-time cost of \$7 million and a total annual cost of approximately \$6 million for CAHs nationwide.

TABLE 1—SUMMARY OF INFORMATION COLLECTION BURDENS

Regulation section(s)	OMB Control No.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Hourly labor cost of reporting (\$)	Total cost (\$)
§ 482.43(a)	0938-XXXX	4,900	4,900	8	39,200	67	2,626,400
§ 482.43(a)	0938-XXXX	4,900	4,900	8	39,200	174	6,820,800
§ 482.43(a)	0938-XXXX	4,900	4,900	8	39,200	187	7,330,400
§ 482.43(b)	0938-XXXX	4,900	13,000,000	0.083	1,079,000	99	106,821,000
§ 484.58(a)	0938-XXXX	11,930	11,930	8	95,440	67	6,394,480
§ 484.58(a)	0938-XXXX	11,930	11,930	8	95,440	98	9,353,120
§ 484.58(a)	0938-XXXX	11,930	11,930	8	95,440	187	17,847,280
§§ 484.58(a) & (b)	0938-XXXX	11,930	18,000,000	0.033	594,000	187	111,078,000
§§ 484.58(a) & (b)	0938-XXXX	11,930	18,000,000	0.05	900,000	52	46,800,000
§§ 484.58(a) & (b)	0938-XXXX	11,930	18,000,000	0.083	1,494,000	67	100,098,000
§§ 484.58(a) & (b)	0938-XXXX	11,930	18,000,000	0.042	756,000	32	24,192,000
§ 485.642(b)	0938-XXXX	1,328	1,328	16	21,248	67	1,423,616
§ 485.642(b)	0938-XXXX	1,328	1,328	16	21,248	187	3,973,376
§ 485.642(b)	0938-XXXX	1,328	1,328	16	21,248	98	2,082,304
§ 485.642(c)	0938-XXXX	1,328	120,000	0.083	9,960	94	936,240
§ 485.642(c)	0938-XXXX	1,328	30,000	0.033	990	187	185,130
§ 485.642(d)	0938-XXXX	1,328	60,000	0.5	30,000	67	2,010,000
§ 485.642(d)	0938-XXXX	1,328	60,000	0.083	4,980	141	702,180
§ 485.642(e)	0938-XXXX	1,328	600,000	0.05	30,000	67	2,010,000
Total		18,158	85,924,474		5,366,594		453,520,660

Note: **There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 1.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: CMS Desk Officer, CMS-3317-P, Fax: (202) 395-6974; or, Email: OIRA_submission@omb.eop.gov.

IV. Regulatory Impact Analysis

A. Statement of Need

Discharge planning is an important component of successful transitions from acute care hospitals and PAC settings, as we have previously discussed. It is universally agreed to be an essential function of hospitals. The transition may be to a patient's home (with or without PAC services), skilled nursing facility or nursing home, long term care hospital, rehabilitation facility, assisted living center, hospice, or a variety of other settings. The location to which a patient may be discharged should be based on the patient's clinical care requirements, available support network, and patient and caregiver treatment preferences and goals of care.

Although the current hospital discharge planning process meets the needs of many inpatients released from the acute care setting, some discharges

result in less-than optimal outcomes for patients including complications and adverse events that lead to hospital readmissions. Reducing avoidable hospital readmissions and patient complications presents an opportunity for improving the quality and safety of patient care, while potentially reducing health care costs. Executive Order 13563 expressly states, in its section on retrospective review, that "agencies shall consider how best to promote retrospective analysis of rules that may be outmoded, ineffective, insufficient, or excessively burdensome, and to modify, streamline, expand, or repeal them in accordance with what has been learned."

We believe that the provisions of the IMPACT Act that require hospitals, CAHs, and PAC providers take into account quality measures and resource use and other measures to assist patients and their families during the discharge planning process will encourage patients and their families to become active participants in the planning of their transition from the hospital to the PAC setting (or between PAC settings). This requirement will allow patients and their families' access to information that will help them to make informed decisions about their post-acute care, while addressing their goals of care and treatment preferences. Patients and their families that are well informed of their choices of high-quality PAC providers may reduce their chances of being re-hospitalized.

Equally importantly, the necessity of meeting this new legislative requirement provides an opportunity to meet the requirement for retrospective review of an important set of regulatory requirements that have not been systematically reviewed in decades. Finally, recent findings about health care delivery problems related to hospitalization, including discharge and readmissions, have indicated that major problems exist. For example, the Institute of Medicine study *To Err is Human* found that failure to properly manage and reconcile medications is a major problem in hospitals (see summary discussion at <https://iom.nationalacademies.org/Reports/1999/To-Err-is-Human-Building-A-Safer-Health-System.aspx>).

B. Overall Impact

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

Executive Orders 12866 and 13563 direct agencies to assess all costs and

benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a “significant regulatory action” as an action that is likely to result in a rule: (1) (Having an annual effect on the economy of \$100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as “economically significant”); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering

the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President’s priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). We estimate that this rulemaking is “economically significant” as measured by the \$100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a RIA that, taken together with the ICR section and other sections of the preamble, presents our best estimates of the effects costs and benefits of the rulemaking.

The Congressional Review Act, 5 U.S.C. 801 *et. seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. HHS will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**.

This proposed rule would create both one-time and annual costs for CAHs and HHAs. The financial costs are summarized in the table that follows. We welcome public comments on all of our burden assumptions and estimates.

TABLE 2—SECTION-BY-SECTION ECONOMIC IMPACT ESTIMATES*

Provider/Supplier	Frequency	Number of affected entities	Likely (\$ millions)
Hospitals (\$ 482.43)	One-time	4,900	17
	Recurring Annually		107
CAHs (\$ 485.642)	One-time	1,328	7
	Recurring Annually		6
HHAs (\$ 484.58)	One-time	11,930	34
	Recurring Annually		283
Total Costs in First Full Year			454

* This table includes entries only for those proposed reforms that we believe would have a measurable economic effect; includes estimates from ICRs and RIA sections. All estimates are rounded to the nearest million.

C. Anticipated Effects

1. Effects on Hospitals (Including LTCHs and IRFs), CAHs, and HHAs

We have accounted for the regulatory impact of these proposed changes through the analysis of costs contained in the ICR sections previously mentioned in this proposed rule. We believe these estimates encompass all additional burden on hospitals, CAHs and HHAs. Any burden associated with the proposed changes to the CoPs not accounted for in the ICR sections or in the RIA section was omitted because we believe it would constitute a usual and customary business practice and would not be subject to the PRA in accordance with 5 CFR 1320.3(b)(2). Nor would it constitute an added cost for purposes of RIA estimates if we added a regulatory requirement that reflected existing practices and workload. We note that we do not estimate costs for the newly added requirement to present quality and cost information to those hospital patients who face a decision on selection of post-discharge providers. In

our view, hospitals already counsel patients on these choices, and the availability of written quality information will not add significantly to the time involved, and may in some cases reduce it (the information, of course, would only be presented as pertinent to the particular decisions facing particular patients). Indeed, all providers affected by this rule already have access to quality information from the CMS Web sites Hospital Compare, Nursing Home Compare, and Home Health Compare, as well as other public and private Web sites and their own knowledge of local providers, and presumably many or most use this information as appropriate to counsel patients. If readers believe we have omitted some category of cost by incorrectly assuming it is already being performed, or to have unnecessarily presented cost estimates for functions that are already being performed, we would welcome comments on these areas of the proposed rule.

Our estimates of the effects of this regulation are subject to significant

uncertainty. While the Department of Health and Human Services is confident that these proposals will provide flexibilities to facilities that will minimize cost increases, there are uncertainties about the magnitude of the discussed effects. However, we have based our overall assumptions and best estimates on our ongoing experiences with hospitals, CAHs, and HHAs in these matters. We welcome public comments on these assumptions and estimates.

In addition, as we previously explained, there may be significant additional health benefits, such as the reduction in patient readmissions after discharges and the reduction of other post-discharge patient complications.

2. Effects on Small Entities

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that the great majority of the providers that would be affected by our

rules are small entities as that term is used in the RFA. The great majority of hospitals and most other healthcare providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business. Accordingly, the usual practice of HHS is to treat all providers and suppliers as small entities in analyzing the effects of our rules.

As shown in table 1, we estimate that the recurring costs of this proposed rule would cost affected entities approximately \$396 million a year (out of the total first year cost of \$454 million a year). A majority of these costs would impact HHAs. While this is a large amount in total, the average annual costs per affected HHA are only about \$24,000 per year (\$283 million in total for all HHAs/11,930 HHAs). Although the overall magnitude of the paperwork, staffing, and related costs to HHAs under this rule is economically significant, these costs are about 1 percent of total HHA costs. According to the 2014 Annual Report of the Medicare trustees, the total annual spending on HHA services from Medicare Parts A and B, not including private payments, was \$18.4 billion in 2013. Our estimated annual cost is 1.5 percent of that total (\$283 million/\$18.4 billion), and as a per patient cost would be approximately that same percentage (less, if private spending were included) for all HHAs. Accordingly, we have concluded that the costs of this proposed rule will not reach 3 percent of revenues, the threshold used by HHS to determine whether a proposed rule is likely to create a negative “significant impact on a substantial number of small entities,” and thereby trigger the requirement for an initial Regulatory Flexibility Analysis.

Effects on hospitals are far smaller, and estimated to be about \$107 million annually in recurring costs. Total annual expenses for all hospitals are about \$859 billion a year.⁹ The estimated costs of this rule would be approximately one hundredth of one percent of this expenditure amount and, since revenues and costs are roughly equal, an equally small percent of revenues.

Total national CAH revenues from Medicare are approximately \$9 billion a year, or an average of about \$7 million annually per hospital (\$9 billion/1,328). We believe that all or almost all CAHs meet the size threshold for small entities. We estimate that this proposed rule would impose costs of

approximately \$6 million nationally, or about \$4,600 per hospital (revenue data from MEDPAC report “Critical Access Hospitals Payment System” at <http://www.medpac.gov/documents/payment-basics/critical-access-hospitals-payment-system-14.pdf?sfvrsn=0>). Assuming conservatively that one-half of all CAH patients are Medicare beneficiaries, and that Medicare accounts for a like percentage of revenues, this would be a small fraction of 1 percent of annual revenues (or, as is roughly equivalent, annual costs). The HHS threshold used for determining significant economic effect on small entities is 3 percent of costs.

Accordingly, after a review of cost effects on HHAs, hospitals, and CAHs, we have determined that this proposed rule would not have a significant economic impact on a substantial number of small entities, and certify that an initial RFA is not required.

We note that quite apart from the gross costs of compliance being a small fraction of revenues or costs of affected entities, net costs will be far smaller. Payment for hospital inpatient services for Medicare beneficiaries is paid primarily according to Medicare severity diagnosis-related groups (MS-DRGs), and MS-DRGs for hospital procedures are periodically revised to reflect the latest estimates of costs from hospitals themselves, as well as from other sources. Hence, absent offsetting effects from other payment changes, and depending on hospitals’ success in controlling overall costs, some portion of these costs will be recovered from Medicare. Moreover, hospitals can and do periodically revise their charges to private insurance carriers (subject in part to negotiations over rates) and for the approximately half of all patients who are “private pay” cost increases can be partially offset in that way. As for CAHs, they are largely paid on a cost basis for their Medicare patients, and will presumably be able to recoup additional costs through periodic adjustments to public and private payment rates. Finally, HHAs also obtain periodic changes in payment rates from both public and private payers. In all three cases, we have no way to predict precise future pathways or exact timing however, we believe that most of the recurring costs (and almost all in the case of CAHs) will be recovered through payments from third party payers, public and private.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to

the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. For the preceding reasons, we have determined that this proposed rule does not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2015, that is approximately \$157 million. This proposed rule would require HHA spending in excess of that threshold, at least in early years before subsequent payment rate increases may take increased costs into account. Mandated spending for CAHs, in contrast, is largely reimbursed on a cost basis and would not count as an unfunded mandate. This RIA and the preamble as presented together here in this proposed rule meet the UMRA requirements for analysis.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues a proposed rule (and subsequent final rule) that would impose substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule would not have a substantial direct effect on state or local governments, preempt states, or otherwise have a Federalism implication.

3. Effects on Patients and Medical Care Costs

Patients in all three settings are the major beneficiaries of this rule. Research cited earlier in this preamble strongly suggests that there would be reductions in morbidity and mortality from improving services to these patients through improved discharge planning. We are unable to quantify either the volume or dollar value of expected benefits. We are not aware of reliable empirical data on the benefits of improved discharge planning. In addition, there are multiple initiatives affecting the same patients (for example, the Hospital Readmissions Reduction Program, the Medicare EHR Incentive Program, and the Accountable Care Organizations under the Medicare Shared Savings Program). This makes it challenging to sort out the separable benefits of this proposed rule.

⁹ <http://www.aha.org/research/rc/stat-studies/fast-facts.shtml>

Nonetheless, the number of patients potentially benefitting is significant. There are roughly 35 million inpatient discharges from hospitals annually. In addition, there are approximately 32 million patients newly affected by substantially modified discharge planning requirements (this figure includes an additional 13 million annual hospital outpatient discharges, 18 million annual HHA patient discharges, and 600,000 annual CAH discharges). If mortality or serious morbidity were prevented for even a fraction of 1 percent of these nearly 50 million patients, potentially tens or hundreds of thousands of persons would substantially benefit.

There are existing requirements in place for discharge planning and for reducing adverse events such as hospital readmissions, both in regulations governing patient care and in payment regulations, but little or no data on the effectiveness of these requirements compared to the normal effects of good medical practice. The changes that would be implemented by this proposed rule are an additional overlay on top of existing practices and requirements. It is challenging to disentangle all these overlapping factors. Therefore, existing data demonstrate that even small improvements can have effects as large as those previously suggested in this proposed rule. For example, one meta-analysis showed that transitional care that promotes the safe and timely transfer of patients from hospital to home has been proven to be highly effective in reducing readmissions.¹⁰ We welcome comments that would provide evidence in regard to these findings.

D. Alternatives Considered

As we previously stated in this proposed rule, some of these provisions are mandated under the IMPACT Act, therefore, no major alternatives were considered. For the other proposed provisions, we considered not making these changes. We did not consider additional requirements that we did not believe would result in substantial benefits at reasonable cost. For example, we considered requiring specific post-

discharge follow-up procedures, but concluded that the range of procedures is so great (including, for example, such very low cost procedures as automatically generated text or email reminders about medication compliance, and such high cost procedures as home visits by nurses), and the range of patient situations so wide (including in many cases no likely benefit from follow-up and in others no efficient way to predict likely benefits), that no reasonable or practicable requirement could be devised at this time. Of course, we encourage providers to use follow-up procedures they find cost-effective for particular categories of patients. We welcome comments and data on these or other follow-up alternatives that may have been shown to be cost-effective in discharge planning, and on what form and with what enforcement standards a mandatory requirement might reasonably use.

We also considered proposing mandatory use of the approximately 50 state-run PDMPs by providers regulated under this proposed rule (each state has its own version and operational, security, access, and other details vary by state). Where hospitals in particular states voluntarily use such programs based on their own determination of utility, we strongly encourage use of such systems. PDMPs have proven useful for law enforcement purposes and, in some states, for pharmacy use. There are, however, uncertainties as to use in hospital settings. As one recent study stated, “whether mandates should become a best practice depends on proving their [PDMP] feasibility and benefits.”¹¹ As discussed earlier in the preamble, there are also questions about “legal, technical, privacy, or security challenges” of provider use of PDMPs, including difficulties of use with EHRs.¹² Regardless, we need current information on whether and where PDMPs have been used effectively and at reasonable cost in hospital discharge planning.¹³ Accordingly, we solicit comments that provide specific information on the feasibility, costs, and patient benefits of using PDMP systems in hospital discharge planning, and on workable implementation and

enforcement standards for a possible mandatory requirement.

For all provisions, we attempted to minimize unnecessarily prescriptive methods or procedures, and to avoid any unnecessarily costly requirements. We welcome comments on whether we properly selected the best provisions for change and on whether there are alternatives or improvements to the proposed provisions that would increase benefits at reasonable cost or reduce costs without compromising important benefits.

E. Cost to the Federal Government

If these requirements are finalized, CMS will update the interpretive guidance, update the survey process, and provide training. In order to implement these new standards, we anticipate initial federal startup costs between \$8 to \$10 million. The continuing costs (survey process-recertifications, enforcement, appeals, AO) are estimated \$4,461,131 and will continue annually, thereafter. CMS will continue to examine and seeks comment on the potential impacts to both Medicare and Medicaid.

F. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 2 we present an accounting statement showing the classification of the costs and benefits associated with the provisions of this final rule. The accounting statement is based on estimates provided in this regulatory impact analysis. We have used as an estimating horizon a 5 year period, but expect that annualized costs would remain essentially the same over a longer period, after the initial year. For purposes of this table, we have used a low estimate that is 25 percent lower than our primary estimate, and a high estimate that is 25 percent higher than our primary estimate. As previously discussed, we have no empirical data or results from previous studies that would allow a defensible estimate of annualized benefits in terms of morbidity and mortality prevented, and medical costs avoided.

¹⁰ Kim J. Verhaegh et al., “Transitional Care Interventions Prevent Hospital Readmissions for Adults with Chronic Illnesses,” *Health Affairs*, 33, no. 9 (2014):1531–1539.

¹¹ Thomas Clark, John Eadie, Peter Kreiner, and Gail Strickler. *Prescription Drug Monitoring Programs: An Assessment of the Evidence for Best Practices*. A study prepared for the PEW Charitable Trusts. September 20, 2012. At: http://www.pdmpexcellence.org/sites/all/pdfs/Brandeis_PDMP_Report_final.pdf.

¹² HHS report to the Congress, *Prescription Drug Monitoring Program Interoperability Standards*, September 2013, section on “Assessment of Legal, Technical, Fiscal, Privacy, and Security Challenges,” at https://www.healthit.gov/sites/default/files/jdasia1141report_final.pdf.

¹³ See the case studies in the 2013 report *Connecting for Impact: Integrating Health IT and PDMPs to Improve Patient Care*, The Mitre Corporation, at https://www.healthit.gov/sites/default/files/connecting_for_impact-final-508.pdf, https://www.healthit.gov/sites/default/files/connecting_for_impact-final-508.pdf.

TABLE 2—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS AND BENEFITS
[\$ In millions]

Category	Primary estimate	Low estimate	High estimate	Units		
				Year dollars	Discount rate (%)	Period covered
Benefits—Qualitative not quantitative or monetized	Potential Reductions in morbidity, mortality, and medical costs for hospital, HHA, and CAH patients.					
Costs—Annual Monetized Costs of Discharge Planning to Medical Care Providers	\$420 410	\$310 310	\$510 510	2015 2015	7 3	2016–20 2016–20
Transfers	None.					

This proposed rule was reviewed by the Office of Management and Budget.

V. Response to Comments

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

List of Subjects

42 CFR Part 482

Grant Programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 484

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

42 CFR Part 485

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

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

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 1. The authority citation for part 482 is revised to read as follows:

Authority: Secs. 1102, 1871, 1881, 1899B of the Social Security Act (42 U.S.C. 1302, 1395hh, 1395rr, and 1395lll) unless otherwise noted.

■ 2. Section 482.43 is revised to read as follows:

§ 482.43 Condition of participation: Discharge planning.

The hospital must develop and implement an effective discharge planning process that focuses on the patient’s goals and preferences and prepares patients and their caregivers/support person(s), to be active partners in post-discharge care, planning for post-discharge care that is consistent with the patient’s goals for care and treatment preferences, effective transition of the patient from hospital to post-discharge care, and the reduction of factors leading to preventable hospital readmissions.

(a) *Standard: Design.* The discharge planning process policies and procedures must meet the following requirements:

- (1) Be developed with input from the hospital’s medical staff, nursing leadership as well as other relevant departments;
- (2) Be reviewed and approved by the governing body; and
- (3) Be specified in writing.

(b) *Standard: Applicability.* The discharge planning process must apply to:

- (1) All inpatients;
- (2) Outpatients receiving observation services;
- (3) Outpatients undergoing surgery or other same day procedures for which anesthesia or moderate sedation are used;
- (4) Emergency department patients identified in accordance with the hospital’s discharge planning policies and procedures by the emergency department practitioner responsible for the care of the patient as needing a discharge plan; and
- (5) Any other category of outpatients as recommended by the medical staff and specified in the hospital’s discharge planning policies and procedures approved by the governing body.

(c) *Standard: Discharge planning process.* The hospital’s discharge

planning process must ensure that the discharge goals, preferences, and needs of each patient are identified and result in the development of a discharge plan for each patient in accordance with paragraph (b) of this section.

(1) A registered nurse, social worker, or other personnel qualified in accordance with the hospital’s discharge planning policies must coordinate the discharge needs evaluation and development of the discharge plan.

(2) The hospital must begin to identify the anticipated discharge needs for each applicable patient within 24 hours after admission or registration, and the discharge planning process is completed prior to discharge home or transfer to another facility and without unduly delaying the patient’s discharge or transfer. If the patient’s stay is less than 24 hours, the discharge needs for each applicable patient must be identified and the discharge planning process completed prior to discharge home or transfer to another facility and without unnecessarily delaying the patient’s discharge or transfer.

(3) The hospital’s discharge planning process must require regular re-evaluation of the patient’s condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(4) The practitioner responsible for the care of the patient must be involved in the ongoing process of establishing the patient’s goals of care and treatment preferences that inform the discharge plan.

(5) The hospital must consider caregiver/support person and community based care availability and the patient’s or caregiver’s/support person’s capability to perform required care including self-care, care from a support person(s), follow-up care from a community based provider, care from post-acute care practitioners and facilities, or, in the case of a patient

admitted from a long term care facility or other residential facility, care in that setting, as part of the identification of discharge needs. The hospital must consider the following in evaluating a patient's discharge needs, including but not limited to:

- (i) Admitting diagnosis or reason for registration;
- (ii) Relevant co-morbidities and past medical and surgical history;
- (iii) Anticipated ongoing care needs post-discharge;
- (iv) Readmission risk;
- (v) Relevant psychosocial history;
- (vi) Communication needs, including language barriers, diminished eyesight and hearing, and self-reported literacy of the patient, patient's representative or caregiver/support person(s), as applicable;
- (vii) Patient's access to non-health care services and community based care providers; and
- (viii) Patient's goals and treatment preferences.

(6) The patient and caregiver/support person(s) must be involved in the development of the discharge plan, and informed of the final plan to prepare them for post-hospital care.

(7) The discharge plan must address the patient's goals of care and treatment preferences.

(8) The hospital must assist the patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The hospital must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(9) The evaluation of the patient's discharge needs and the resulting discharge plan must be documented and completed on a timely basis, based on the patient's goals, preferences, strengths, and needs, so that appropriate arrangements for post-hospital care are made before discharge to avoid unnecessary delays in discharge.

(i) The discharge plan must be included in the patient's medical record. The results of the evaluation must be discussed with the patient or patient's representative.

(ii) All relevant patient information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the patient's discharge or transfer.

(10) The hospital must assess its discharge planning process on a regular basis. The assessment must include

ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs.

(d) *Standard: Discharge to home.* (1) Discharge instructions must be provided at the time of discharge to:

- (i) The patient and/or the patient's caregiver/support person(s), and
- (ii) The post-acute care provider or supplier, if the patient is referred to post-acute care services.

(2) The discharge instructions must include, but are not limited to, the following:

(i) Instruction on post-hospital care to be used by the patient or the caregiver/support person(s) in the patient's home, as identified in the discharge plan;

(ii) Written information on warning signs and symptoms that may indicate the need to seek immediate medical attention. This must include written instructions on what the patient or the caregiver/support person(s) should do and who they should contact if these warning signs or symptoms present;

(iii) Prescriptions and over-the-counter medications that are required after discharge, including the name, indication, and dosage of each drug, along with any significant risks and side effects of each drug as appropriate to the patient;

(iv) Reconciliation of all discharge medications with the patient's pre-hospital admission/registration medications (both prescribed and over-the-counter); and

(v) Written instructions in paper and/or electronic format regarding the patient's follow-up care, appointments, pending and/or planned diagnostic tests, and pertinent contact information, including telephone numbers, for any practitioners involved in follow-up care or for any providers/suppliers to whom the patient has been referred for follow-up care.

(3) The hospital must send the following information to the practitioner(s) responsible for follow up care, if the practitioner is known and has been clearly identified:

(i) A copy of the discharge instructions and the discharge summary within 48 hours of the patient's discharge;

(ii) Pending test results within 24 hours of their availability;

(iii) All other necessary information as specified in § 482.43(e)(2).

(4) The hospital must establish a post-discharge follow-up process.

(e) *Standard: Transfer of patients to another health care facility.* (1) The

hospital must send necessary medical information to the receiving facility at the time of transfer.

(2) Necessary medical information must include:

(i) Demographic information, including but not limited to name, sex, date of birth, race, ethnicity, preferred language;

(ii) Contact information for the practitioner responsible for the care of the patient, as described at paragraph (b)(4) of this section, and the patient's caregiver(s)/support person(s), if applicable;

(iii) Advance directive, if applicable;

(iv) Course of illness/treatment;

(v) Procedures;

(vi) Diagnoses;

(vii) Laboratory tests and the results of pertinent laboratory and other diagnostic testing;

(viii) Consultation results;

(ix) Functional status assessment;

(x) Psychosocial assessment, including cognitive status;

(xi) Social supports;

(xii) Behavioral health issues;

(xiii) Reconciliation of all discharge medications with the patient's pre-hospital admission/registration medications (both prescribed and over-the counter);

(xiv) All known allergies, including medication allergies;

(xv) Immunizations;

(xvi) Smoking status;

(xvii) Vital signs;

(xviii) Unique device identifier(s) for a patient's implantable device(s), if any;

(xix) All special instructions or precautions for ongoing care, as appropriate;

(xx) Patient's goals and treatment preferences; and

(xxi) All other necessary information including a copy of the patient's discharge instructions, the discharge summary and any other documentation as applicable, to ensure a safe and effective transition of care that supports the post-discharge goals for the patient.

(f) *Standard: Requirements for post-acute care services.* For those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, the following requirements apply, in addition to those set out at paragraphs (a) through (d) of this section:

(1) The hospital must include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the

case of a SNF, IRF, or LTCH, in the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care post-hospital extended care services, SNF, IRF, or LTCH services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must make the patient aware of the need to verify with their managed care organization which practitioners, providers or certified suppliers are in the managed care organization's network. If the hospital has information on which practitioners, providers or certified supplies are in the network of the patient's managed care organization, it must share this with the patient or the patient's representative.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the patient's representative.

(2) The hospital, as part of the discharge planning process, must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services and must, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express. The hospital must not specify or otherwise limit the qualified providers or suppliers that are available to the patient.

(3) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of part 420, subpart C, of this chapter.

PART 484—HOME HEALTH SERVICES

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

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

■ 4. Section 484.58 is added to subpart C to read as follows:

§ 484.58 Condition of participation: Discharge Planning.

A Home Health Agency (HHA) must develop and implement an effective

discharge planning process that focuses on preparing patients to be active partners in post-discharge care, effective transition of the patient from HHA to post-HHA care, and the reduction of factors leading to preventable readmissions.

(a) *Standard: Discharge planning process.* The HHA's discharge planning process must ensure that the discharge goals, preferences, and needs of each patient are identified and result in the development of a discharge plan for each patient.

(1) The discharge planning process must require regular re-evaluation of patients to identify changes that require modification of the discharge plan, in accordance with the provisions for updating the patient assessment at § 484.55. The discharge plan must be updated, as needed, to reflect these changes.

(2) The physician responsible for the home health plan of care must be involved in the ongoing process of establishing the discharge plan.

(3) The HHA must consider caregiver/support person availability, and the patient's or caregiver's capability to perform required care, as part of the identification of discharge needs.

(4) The patient and caregiver(s) must be involved in the development of the discharge plan, and informed of the final plan.

(5) The discharge plan must address the patient's goals of care and treatment preferences.

(6) For patients who are transferred to another HHA or who are discharged to a SNF, IRF, or LTCH, the HHA must assist patients and their caregivers in selecting a post-acute care provider by using and sharing data that includes, but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The HHA must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(7) The evaluation of the patient's discharge needs and discharge plan must be documented and completed on a timely basis, based on the patient's goals, preferences, and needs. The discharge plan must be included in the clinical record. The results of the evaluation must be discussed with the patient or patient's representative. All relevant patient information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the patient's discharge or transfer.

(b) *Standard: Discharge or transfer summary content.* The HHA must send

necessary medical information to the receiving facility or health care practitioner. Necessary medical information must include:

(1) Demographic information, including but not limited to name, sex, date of birth, race, ethnicity, preferred language;

(2) Contact information for the physician responsible for the home health plan of care;

(3) Advance directive, if applicable;

(4) Course of illness/treatment;

(5) Procedures;

(6) Diagnoses;

(7) Laboratory tests and the results of pertinent laboratory and other diagnostic testing;

(8) Consultation results;

(9) Functional status assessment;

(10) Psychosocial assessment, including cognitive status;

(11) Social supports;

(12) Behavioral health issues;

(13) Reconciliation of all discharge medications (both prescribed and over-the-counter);

(14) All known allergies, including medication allergies;

(15) Immunizations;

(16) Smoking status;

(17) Vital Signs;

(18) Unique device identifier(s) for a patient's implantable device(s), if any;

(19) Recommendations, instructions, or precautions for ongoing care, as appropriate;

(20) Patient's goals of care and treatment preferences;

(21) The patient's current plan of care, including goals, instructions, and the latest physician orders; and

(22) Any other information necessary to ensure a safe and effective transition of care that supports the post-discharge goals for the patient.

PART 485—CONDITIONS OF PARTICIPATION SPECIALIZED PROVIDERS

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

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

■ 6. Section 485.635 is amended by adding paragraph (a)(3)(viii) to read as follows:

§ 485.635 Condition of participation: Provision of services.

* * * * *

(a) * * *

(3) * * *

(viii) Discharge planning policies and procedures, in accordance with the requirements of § 485.642.

* * * * *

■ 7. Section 485.642 is added to read as follows:

§ 485.642 Condition of participation: Discharge planning.

A Critical Access Hospital (CAH) must develop and implement an effective discharge planning process that focuses on preparing patients to participate in post-discharge care, planning for post-discharge care that is consistent with the patient's goals for care and treatment preferences, effective transition of the patient from the CAH to post-discharge care, and the reduction of factors leading to preventable readmissions to a CAH or a hospital.

(a) *Standard: Design.* The discharge planning process policies and procedures must meet the following requirements:

(1) Be developed with input from the CAH's professional healthcare staff, nursing leadership as well as other relevant departments;

(2) Be reviewed and approved by the governing body or responsible individual; and

(3) Be specified in writing.

(b) *Standard: Applicability.* The discharge planning process must apply to:

(1) All inpatients;

(2) Outpatients receiving observation services;

(3) Outpatients undergoing surgery or other same day procedures for which anesthesia or moderate sedation are used;

(4) Emergency department patients identified in accordance with the CAH's discharge planning policies and procedures by the emergency department practitioner responsible for the care of the patient as needing a discharge plan; and

(5) Any other category of outpatients as recommended by the medical staff and specified in the CAH's discharge planning policies and procedures approved by the governing body or responsible individual.

(c) *Standard: Discharge planning process.* The CAH's discharge planning process must ensure that the discharge goals, preferences, and needs of each patient are identified and result in the development of a discharge plan for each patient in accordance with paragraph (a) of this section.

(1) A registered nurse, social worker, or other personnel qualified in accordance with the CAH's discharge planning policies must coordinate the discharge needs evaluation and development of the discharge plan.

(2) The CAH must begin to identify the anticipated goals, preferences, and

discharge needs for each applicable patient within 24 hours after admission or registration and the discharge planning process is completed prior to discharge home or transfer to another facility and without unduly delaying the patient's discharge or transfer. If the patient's stay is less than 24 hours, the discharge needs for each applicable patient must be identified and the discharge planning process completed prior to discharge home or transfer to another facility and without unnecessarily delaying the patient's discharge or transfer.

(3) The CAH's discharge planning process must require regular re-evaluation of patients to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(4) The practitioner responsible for the care of the patient must be involved in the ongoing process of establishing the patient's goals of care and treatment preferences that inform the discharge plan.

(5) The CAH must consider caregiver/support person and community based care availability, and the patient's or caregiver's/support person's capability to perform required care including self-care, care from a support person(s), follow-up care from a community based provider, care from post-acute care facilities, or, in the case of a patient admitted from a long term care or other residential facility, care in that setting, as part of the identification of discharge needs. The CAH must consider the following in evaluating a patient's discharge needs, including but not limited to:

(i) Admitting diagnosis or reason for registration;

(ii) Relevant co-morbidities and past medical and surgical history;

(iii) Anticipated ongoing care needs post-discharge;

(iv) Readmission risk;

(v) Relevant psychosocial history;

(vi) Communication needs, including language barriers, diminished eyesight and hearing, and self-reported literacy of the patient, patient's representative or caregiver/support person(s), as applicable;

(vii) Patient's access to non-health care services and community based providers; and

(viii) Patient's goals and preferences.

(6) The patient and caregiver/support person(s) must be involved in the development of the discharge plan and informed of the final plan to prepare them for post-CAH care.

(7) The discharge plan must address the patient's goals of care and treatment preferences.

(8) The CAH must assist patients, their families, or their caregivers/support persons in selecting a post-acute care provider by using and sharing data that includes but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The CAH must ensure that the post-acute care data on quality measures and data on resource use measures furnished to the patient is specific to the post-acute care setting(s) and relevant and applicable to the patient's goals of care and treatment preferences.

(9) The evaluation of the patient's discharge needs and the resulting discharge plan must be documented and completed on a timely basis, based on the patient's goals, preferences, strengths, and needs, so that appropriate arrangements for post-CAH care are made before discharge to avoid unnecessary delays in discharge.

(i) The discharge plan must be included in the patient's medical record. The results of the evaluation must be discussed with the patient or patient's representative.

(ii) All relevant patient information must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the patient's discharge or transfer.

(10) The CAH must assess its discharge planning process in accordance with the requirements of § 485.635(a)(4). The assessment must include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission to ensure that the plans are responsive to patient post-discharge needs.

(d) *Standard: Discharge to home.* (1) Discharge instructions must be provided at the time of discharge to:

(i) The patient and/or the patient's caregiver/support person(s), and

(ii) The post-acute care service provider or supplier, if the patient is referred to community-based services.

(2) The discharge instructions must include, but are not limited to, the following:

(i) Instruction on post-discharge care to be used by the patient or the caregiver/support person(s) in the patient's home, as identified in the discharge plan;

(ii) Written information on warning signs and symptoms that may indicate the need to seek immediate medical attention. This must include written instructions on what the patient or the

caregiver/support person(s) should do and who they should contact if these warning signs or symptoms present;

(iii) Prescriptions for medications that are required after discharge, including a list of name, indication, and dosage of each drug, along with any significant risks and side effects of each drug as appropriate to the patient;

(iv) Reconciliation of all discharge medications with the patient's pre-CAH admission/registration medications (both prescribed and over-the-counter); and

(v) Written instructions regarding the patient's follow-up care, appointments, pending and/or planned diagnostic tests, and pertinent contact information, including telephone numbers, for practitioners involved in follow-up care or for any providers/suppliers to whom the patient has been referred for follow-up care.

(3) The CAH must send the following information to the practitioner(s) responsible for follow up care, if the practitioner is known and has been clearly identified:

(i) A copy of the discharge instructions and the discharge summary within 48 hours of the patient's discharge;

(ii) Pending test results within 24 hours of their availability;

(iii) All other necessary medical information as specified in § 485.642(e)(2).

(4) The CAH must establish a post-discharge follow-up process.

(e) *Standard: Transfer of patients to another health care facility.* (1) The CAH must send necessary medical information to the receiving facility at the time of transfer.

(2) Necessary medical information includes:

(i) Demographic information, including but not limited to name, sex, date of birth, race, ethnicity, preferred language;

(ii) Contact information for the practitioner responsible for the care of the patient, as described at paragraph (b)(4) of this section, and the patient's caregiver/support person(s), if applicable;

(iii) Advance directive, if applicable;

(iv) Course of illness/treatment;

(v) Procedures;

(vi) Diagnoses;

(vii) Laboratory tests and the results of pertinent laboratory and other diagnostic testing;

(viii) Consultation results;

(ix) Functional status assessment;

(x) Psychosocial assessment, including cognitive status;

(xi) Social supports;

(xii) Behavioral health issues;

(xiii) Reconciliation of all discharge medications with the patient's pre-CAH admission/registration medications (both prescribed and over-the-counter);

(xiv) All known allergies, including medication allergies;

(xv) Immunizations;

(xvi) Smoking status;

(xvii) Vital signs;

(xviii) Unique device identifier(s) for a patient's implantable device(s), if any;

(xix) All special instructions or precautions for ongoing care, as appropriate;

(xx) Patient's goals and treatment preferences; and

(xxi) Any other necessary information including a copy of the patient's discharge instructions, the discharge summary, and any other documentation as applicable, to ensure a safe and effective transition of care that supports the post-discharge goals for the patient.

Dated: October 19, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: October 22, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015-27840 Filed 10-29-15; 8:45 am]

BILLING CODE 4120-01-P