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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 482, 484, and 485

[CMS-3317-F and CMS-3295-F]

RIN 0938-AS59

Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care

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

ACTION: Final rule.

SUMMARY: This final rule empowers patients to be active participants in the discharge planning process and complements efforts around interoperability that focus on the seamless exchange of patient information between health care settings by revising the discharge planning requirements that Hospitals (including Short-Term Acute-Care Hospitals, Long-Term Care Hospitals (LTCHs), Rehabilitation Hospitals, Psychiatric Hospitals, Children's Hospitals, and Cancer Hospitals), Critical Access Hospitals (CAHs), and Home Health Agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. This final rule also implements discharge planning requirements which will give 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, which may ultimately reduce their chances of

being re-hospitalized. It also updates one provision regarding patient rights in hospitals, intended to promote innovation and flexibility and to improve patient care.

DATES: These regulations are effective on [Insert date 60 days after the date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Alpha-Banu Wilson, (410) 786-8687, Kianna Banks, (410) 786-3498,

CAPT Scott Cooper, USPHS, (410) 786-9465, Eric Laib (410) 786-9759, and Danielle Shearer, (410) 786-6617.

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.

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I. Background

A. Overview

On November 3, 2015, we published a proposed rule that would update the discharge planning requirements for hospitals, critical access hospitals (CAHs), and post-acute care (PAC) settings (80 FR 68126). Discharge planning is an important component of a successful transition from hospitals and PAC settings. The transition may be to a patient's home (with or without PAC services), skilled nursing facility (SNF), nursing facility (NF), long term care hospital (LTCH), rehabilitation hospital or unit, assisted living center, substance abuse treatment program, hospice, or a variety of other settings. While Medicare regulations define "post-acute care" providers to include SNFs, LTCHs,

inpatient rehabilitation facilities (IRFs) and home health agencies (HHAs), it should be noted that there are other services that can be provided by entities other than PAC providers (that is, LTCHs, IRFs, HHAs, and SNFs), including assisted living facilities, home and community-based services, or primary care providers. 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.

We also proposed to implement the discharge planning requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113-185), that requires hospitals, including, but not limited to, short-term acute care hospitals, CAHs and PAC providers (LTCHs, IRFs, HHAs, and SNFs), to take into account quality measures and resource use measures to assist patients and their families during the discharge planning process in order to encourage patients and their families to become active participants in the planning of their transition to the PAC or other settings (or between such settings).

We published another proposed rule on June 16, 2016 in the **Federal Register**, titled "Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care" (81 FR 39448), hereinafter referred to as the "Hospital Innovation proposed rule", that proposed to update a number of Conditions of Participation (CoP) requirements that hospitals and CAHs must meet in order to participate in the Medicare and Medicaid programs. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients and patient access to their medical records. We proposed that patients

have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the patient, including current medical records, within a reasonable time frame. The hospital could not frustrate the legitimate efforts of patients to gain access to their own medical records and would have to actively seek to meet these requests as quickly as its record keeping system permitted.

In accordance with Executive Order 13813, which promotes healthcare choice and competition across the country, and in line with HHS' goals to improve interoperability between patients and their health care providers, we are finalizing certain discharge planning requirements for hospitals (including Short-Term Acute-Care Hospitals, LTCHs, Rehabilitation Hospitals, Psychiatric Hospitals, Children's Hospitals, and Cancer Hospitals), HHAs, and CAHs as well as finalizing the hospital patients' rights requirement regarding patient access to medical records. We are also finalizing the requirements of the IMPACT Act for hospitals, HHAs, and CAHs. We believe that these final requirements will empower patients to be active participants in the discharge planning process and will help them to make informed choices about their care, which may lead to more competition, lower costs, and improved quality of care. Furthermore, the IMPACT Act requirements will give 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 who

are well informed of their choices of high-quality PAC providers may reduce their chances of being re-hospitalized.

We also believe these final requirements will complement efforts around interoperability that focus on the seamless exchange of patient information between health care settings. Ultimately, these final requirements will ensure that a patient's health care information follows them after discharge from a hospital or PAC provider to their receiving health care facility, medical professional, or caregiver, as applicable.

B. IMPACT Act

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 section 1899B to the Social Security Act (the Act). Section 1899B of the Act 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 of the IMPACT Act varies for the standardized assessment data described in subsection (b) of the Act, data on quality measures described in subsection (c) of the Act, and data on resource use and other measures described in subsection (d) of section 1899B of the Act. We note that many of these PAC provisions are being addressed in separate rulemakings. More information can be found on the CMS website at: https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/IMPACT-Act-of-2014-Data-Standardization-and-Cross-Setting-Measures.html.

Section 1899B(j) of the Act requires that we allow for stakeholder input, such as through town hall meetings, open door forums, and mailbox submissions, before the initial rulemaking process to implement section 1899B of the Act. To meet this requirement, we provided the following opportunities for stakeholder input: (1) on February 3, 2015 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; (2) provided two separate listening sessions on February 10 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; (3) in January 2015 we implemented a public mail box for the submission of comments located at PACQualityInitiative@cms.hhs.gov. The CMS public mailbox can be accessed on our PAC quality initiatives website:

https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Post-Acute-Care-Quality-Initiatives/IMPACT-Act-of-2014/Submit-a-Question-or-Feedback.html; (4) held a National Stakeholder Special Open Door Forum on February 25, 2015 to seek input on the measures; and (5) sought public input during the February 2015 ad hoc Measure Applications Partnership (MAP) process meeting regarding the measures under consideration with respect to the IMPACT Act domains.

Section 1899B(i) of the Act, which addresses discharge planning, requires the modification of the 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 of the Act in the discharge planning process.

We proposed to implement the discharge planning requirements mandated in section 1899B(i) of the Act by modifying the discharge planning or discharge summary CoPs for hospitals, CAHs and HHAs. As stated above, the IMPACT Act added section 1899B to the Act. 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 hospitals (including their Inpatient Prospective Payment System (IPPS), excluded rehabilitation or psychiatric units), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals) are all classifications of hospitals. All classifications of hospitals (as well as distinct part psychiatric and rehabilitation units in CAHs) are subject to most of the same core hospital CoPs. Therefore, these PAC providers (including freestanding LTCHs and IRFs) are also subject to the revisions to

the hospital CoPs. We finalized the discharge planning requirements for SNFs and NFs in a final rule published on October 4, 2016 in the **Federal Register**, titled "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities" (81 FR 68688). The various providers' compliance with these requirements is assessed through on-site surveys by CMS, State Survey Agencies (SAs) or national accrediting organizations (AOs) that have CMS-approved Medicare accreditation programs.

II. Provisions of the Proposed Regulations and Responses to Public Comments

On November 3, 2015, we published a proposed rule in the **Federal Register**, titled "Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies" (80 FR 68126), hereinafter referred to as the "Discharge Planning proposed rule," that would revise the discharge planning requirements that hospitals (including, but not limited to, LTCHs and IRFs), CAHs, and HHAs must meet in order to participate in the Medicare and Medicaid programs. In addition, we proposed to implement the discharge planning requirements of the IMPACT Act. In response to the proposed rule, we received 299 public comments. Commenters included individuals, health care professionals and corporations, national associations and coalitions, state health departments, patient advocacy organizations, and individual facilities that will be impacted by the rule. Generally, most comments centered on the hospital requirements, but could be applied to all provider types included in the proposed rule. We also received various comments in response to our solicitation for comments related to specific proposals.

In response to the Hospital Innovation proposed rule, we received 200 public comments, of which a small portion were centered on the proposed patient's right to

access his or her own medical information requirement. This proposed revision to the hospital Patients' Rights CoP directly addressed the issues of communication between providers and patients and patient access to their medical records. Therefore, we are finalizing a patients' right provision at 42 CFR 482.13 that we proposed in the Hospital Innovation proposed rule. The provision we are finalizing here ensures a patient's right to access his or her own medical information from a hospital. This is the only provision of that rule that we are finalizing in this final rule. We are continuing to consider comments on the remaining portion of the Hospital Innovation proposed rule, and we will respond to those comments when we finalize that rule in future rulemaking.

In this final rule, we provide a summary of our proposed provisions, a summary of the public comments received and our responses to them, and the policies we are finalizing for hospitals, HHAs, and CAHs. We have organized our proposed provisions and responses to the comments as follows: General comments; Discharge Planning Requirements of the IMPACT Act of 2014; Implementation; Prescription Drug Monitoring Programs; Patients' Rights and Discharge Planning in Hospitals; Home Health Agency Discharge Planning; and Critical Access Hospital Discharge Planning. Except for comments specific to the Hospital Innovation proposed rule, all comments discussed here were submitted in response to the Discharge Planning proposed rule. Comments related to the paperwork burden and impact analysis sections are addressed in section VI, "Regulatory Impact Analysis" of this final rule.

A. General Comments

We received comments suggesting improvements to our regulatory approach or requesting clarification on general issues related to our proposed discharge planning

requirements. The comments and our responses to those general comments are as follows.

Comment: The majority of commenters generally supported standardizing and modernizing the discharge planning requirements for hospitals, including LTCHs and IRFs, HHAs, and CAHs. Individuals, including former patients, health care professionals, and advocacy groups strongly supported more stringent, detailed discharge planning requirements that focus on person-centered care and on the patient's treatment preferences and goals of care. Some of these commenters noted that without these requirements, some discharges from hospitals have been unsafe or inadequate and have led to readmissions or unnecessary emergency department visits shortly after discharge.

However, most commenters disagreed with certain, specific proposed discharge planning requirements. Many of these commenters stated that the requirements were too burdensome or overly prescriptive. Some of these commenters found that the proposed requirements did not go far enough to protect patients. Finally, a few commenters were against new discharge planning requirements altogether.

Response: We believe that these final discharge planning requirements for hospitals, including LTCHs, IRFs, HHAs, and CAHs will improve transitions of care, increase a patient's ability to access their health care information in a timely manner, and complement and align with efforts to improve interoperability across the care continuum. We also believe that these final requirements, which we discuss in further detail in subsequent sections of this final rule, are less burdensome than our initial proposed discharge planning requirements. In addition, we continue to believe in the importance of person-centered care during the discharge planning process. 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.

These final requirements will establish and standardize discharge planning requirements for hospitals, HHAs, and CAHs. We note that effective discharge planning can also help to reduce patient readmissions, improve patient quality of care and outcomes, and reduce avoidable complications, adverse events, and readmissions.

In addition, these regulations will implement the discharge planning requirements of the IMPACT Act, which will empower patients to be active participants in the discharge planning process, which will require providers to give patients more information as they choose a PAC provider. In regards to the commenters' concerns about specific proposed requirements, we refer readers to the specific provider sections and the specific provisions throughout the preamble of this final rule for a more detailed discussion of the final requirements and responses to the comments we received on the proposed rule.

Comment: Several commenters requested clarification on whether the proposed requirements would apply to certain provider types or programs that are not mentioned in the proposed rule. A few commenters questioned whether the proposed discharge planning requirements would apply to inpatient psychiatric facilities, and one commenter asked whether the rule would apply to inpatient psychiatric units. The commenter recommended that CMS explicitly state which provider types would be required to comply with the discharge planning CoPs. One commenter requested clarification as to whether the proposed requirements would apply to partial hospitalization and intensive outpatient programs at hospitals.

Response: All classifications of hospitals except CAHs are regulated under part 482 of our regulations, and are subject to the same set of hospital CoPs. We further clarified that the PAC providers mentioned in the IMPACT Act, specifically LTCHs and IRFs, would also be subject to the proposed revision to the hospital CoPs. We did not list all the classifications of hospitals in the proposed rule since we specifically focused on the PAC providers mentioned in the IMPACT Act, but we understand the importance of delineating which hospital types would have to comply with the hospital discharge planning CoPs, since they were not explicitly mentioned in the proposed rule. Therefore, we are clarifying that these final discharge planning requirements apply to all classifications of hospitals, including short-term acute care hospitals (including their IPPS-excluded rehabilitation or psychiatric units), psychiatric hospitals, LTCHs, rehabilitation hospitals, children's hospitals, and cancer hospitals. Throughout this final rule, we clarify that where the term "hospital" is used, we are referring to the aforementioned hospital classifications. These requirements would also apply to distinct part psychiatric and rehabilitation units in CAHs.

Although these discharge planning requirements apply to psychiatric hospitals, there are several additional currently existing discharge planning requirements specific to psychiatric hospitals that are not affected by the discharge planning requirements discussed in this rule. Thus, psychiatric hospitals will still be required to meet the additional special provisions, special medical record requirements, and special staff requirements set out at §§ 482.60, 482.61, and 482.62.

Inpatient psychiatric units located in a hospital, (as opposed to psychiatric hospitals) are specialized units within a larger hospital or CAH. Inpatient psychiatric

units must meet the hospital CoP requirements for the hospitals in which they are located. However, they are not required to meet the CoPs specific to psychiatric hospitals set out at §§ 482.60, 482.61, and 482.62. Therefore, these discharge planning requirements apply to inpatient psychiatric units located within a hospital or a CAH. The additional, currently existing, discharge planning requirements for psychiatric hospitals do not apply to inpatient psychiatric units. Note that "inpatient psychiatric facility" is a CMS classification used to refer to both psychiatric hospitals and inpatient psychiatric excluded units of hospitals and inpatient psychiatric distinct part units of CAHs; however, psychiatric excluded and distinct part units in hospitals and CAHs are not subject to the requirements under §§ 482.60, 482.61, and 482.62.

In response to the commenter's request for clarification regarding partial hospitalization services and intensive outpatient services at hospitals, we note that these services can be provided in a hospital outpatient department, and partial hospitalization services can be provided in a community mental health center. These discharge planning requirements however would not apply to services provided to patients in a community health center.

Comment: Several commenters were concerned that durable medical equipment (DME) requirements were not specifically required in the discharge planning proposed rule. The commenters explained that providers should address and document a patient's DME needs during the discharge planning process. A few commenters also noted that DME was not addressed in the Meaningful Use Stage 3 requirements (80 FR 62761, which is discussed in our response here), and thus is still largely in paper format.

Response: We agree that considering a patient's DME needs when planning for a patient's post-hospital care is a best practice. While we are not mandating that providers include information on a patient's DME needs in the patient's discharge instructions at this time, we encourage providers to do so where appropriate. However, comments regarding specific Stage 3 Meaningful Use requirements are not within the purview of these CoPs.

Comment: One commenter noted the absence of proposed discharge planning requirements for SNFs in the Discharge Planning proposed rule. One commenter requested that CMS require nursing homes to provide patients with prescriptions before the patient returns home or back to the community. One commenter suggested that LTC facilities and rehabilitation facilities have a social worker with a Master of Science in Management (MSM), Licensed Clinical Social worker (LCSW), or a Master's degree in Gerontology. Another commenter recommended that each state expand the number of nursing facility/acute hospital Medicaid demonstration programs that will allow individuals with disabilities to live in the community.

Response: Comments regarding LTC facilities and Medicaid demonstration programs are outside the scope of this final rule. The discharge planning requirements for SNFs were addressed in the Long-Term Care (LTC) Facility Requirements final rule (81 FR 68688, October 4, 2016) and § 483.21(c) of the SNF requirements, which addresses discharge planning.

Comment: A few commenters recommended that if CMS finalizes the proposed requirements, the final regulation and sub-regulatory guidance should not focus on the process of discharge planning alone, but allow providers greater flexibility to ensure their

efforts are meaningful and adaptable over time. One commenter believed that the proposed rule included too many details on the discharge planning process instead of focusing on outcomes, which the commenter stated, could lead to "performing to the test" activities that inhibit innovation. The commenter noted that the goals of the regulations should instead be focused on holding providers responsible for outcomes and not the processes of care. The commenter noted that CMS already has several programs that focus on outcomes, including value-based payment plans and hospital compare and star rating systems. The commenter ultimately believed that providers should use these mechanisms to drive innovation and lead to the best possible outcomes.

Another commenter expressed concern over the potential impact of the proposed requirements on currently existing state innovation programs aimed at adopting value-based payment. The commenter recommended that CMS review the proposed changes to the CoPs, with support for state flexibility for innovation. Finally, another commenter noted that providers would need support in implementing and understanding the finalized discharge planning requirements.

Response: We understand the commenters' concerns and have revised most of the proposed requirements in this final rule to focus less on prescriptive and burdensome process details, and more on patient outcomes and treatment preferences through the use of enhanced information exchange and innovative practice standards. We encourage hospitals, HHAs, and CAHs to actively engage with patients to create a more meaningful discharge planning process. We believe these requirements will afford patients the opportunity to be active participants in the discharge planning process. In addition, in order to encourage patient engagement and understanding of their discharge plan or

instructions, we recommend that providers follow the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (https://www.thinkculturalhealth.hhs.gov/clas/standards), which provide guidance on providing instructions in a culturally and linguistically appropriate manner. We also remind providers of their obligations take reasonable steps to provide meaningful access to individuals with limited English proficiency in accordance with Title VI of the Civil Rights Act of 1964 and section 1557 of the Patient Protection and Affordable Care Act (the Affordable Care Act). In addition, providers are reminded to take appropriate steps to ensure effective communication with individuals with disabilities, including the provision of auxiliary aids and services, in accordance with section 504 of the Rehabilitation Act, the Americans with Disabilities Act, and section 1557 of the Affordable Care Act (see, http://www.hhs.gov/civil-rights and http://www.ada.gov for more information on these requirements).

We believe that the requirements, as revised here in this final rule, are consistent with the innovation goals of existing programs and initiatives, including the Hospital Value-Based Purchasing Program and the Center for Medicare and Medicaid Innovation's State Innovation Models Initiative.

As with all CoPs, compliance with these requirements will be monitored by CMS, SAs, and AOs through surveys. We understand the commenter's concerns about provider support in implementing and understanding the final discharge planning requirements. We will provide sub-regulatory interpretive guidance after the publication of this final rule, which will provide further clarification for implementing the final discharge planning requirements.

Comment: A few commenters requested changes to the terminology used throughout the proposed rule while others requested that CMS define certain terms used throughout the rule. One commenter requested that CMS use the term "transition management" instead of discharge planning.

A few commenters recommended that CMS replace the term "patient" with "individual," "person" or "affected person," where appropriate, in order to further emphasize the expectation that the discharge planning process should be person-centered.

A few commenters also had suggestions on the definition of "caregiver." One commenter recommended that the proposed rule define the term "caregiver." The commenter noted that several terms are used throughout the proposed rule, including "caregiver," "caregiver/support person," and "family and/or caregiver."

Response: We agree that there are several different types of terminology providers may utilize when referring to some of the concepts used in this rule. We do not agree with changing the terminology currently used in this rule because we are using the most widely accepted and recognized terminology in the medical industry. In addition, the terminology used throughout this rule is used in the Act, including the term "discharge planning process" as set forth in section 1861(ee) of the Act.

In addition, consistent with the language widely used by providers as well as the language used in the CoPs for hospitals, CAHs and HHAs, we continue the use of the term "patient." As a result, we do not believe that it is appropriate to exclusively use "person" or "individual." However, we acknowledge that the use of "person" or "individual" also appropriately refers to a patient, and we have used this terminology at various points in the rule (for example, when referring to person-centered care).

In response to the commenter that requested a definition of "caregiver," we note that we often use the terms "caregiver," "caregiver/support person," and "family and/or caregiver," interchangeably, with the same intended meaning. We use these various terms in order to be consistent with the regulations that already exist for hospitals, HHAs, and CAHs. We do not believe that it is necessary to define the term, as it does not have a special meaning in this rule.

Comment: Several comments were submitted related to the responsibilities of hospitals, HHAs, and CAHs to involve and communicate with caregivers. Commenters recommended the following:

- Require hospitals, HHAs, and CAHs to allow patients at least one opportunity to identify at least one caregiver/support person upon admission and prior to discharge or transfer to another facility, and to collect caregiver telephone contact and email address information when the provider offers the patient an opportunity to designate a caregiver.
- Clarify that providers must make reasonable attempts to contact the patient's identified caregiver during the discharge planning process.
- Require that, if the caregiver contacts the provider after the discharge planning process has begun, that individual must be involved in the discharge planning process.
- Require providers to ask what the preferred method of contact is for the caregiver.
- Require the provider to document all attempted contact with the caregiver.
- Clarify that caregivers and support persons should be involved, as applicable, but that CMS is not expecting that all patients will have caregivers and support

persons and that the extent of the involvement of patients and caregivers be consistent with the patient's wishes and applicable law, including with the HIPAA Privacy Rule.

- Clarify expectations for how providers will address situations where a support person or caregiver is uncooperative, and how hospitals and CAHs should document the involvement of the caregiver and support person.
- Require that caregivers be notified in advance of the individual's discharge in order to ensure a safe and appropriate discharge back to the community.
- Provide caregivers with the name and contact information for the staff in the hospital or CAH, with whom they can discuss any concerns about the discharge plan or changes in the patient's care.
- Require providers to give the caregiver a copy of the final discharge plan, since "informed of the final plan" is not defined.

Response: We appreciate the commenter's concerns regarding the inclusion of the patient's caregiver during the discharge planning process. We continue to strongly believe that a patient's caregiver should be included in the discharge planning process, and have revised the regulations at § 482.43 for hospitals and § 485.642 for CAHs to allow more flexibility for hospitals and CAHs in how such inclusion is achieved. We agree that we would not expect each patient to have a caregiver or support person, and that any level of caregiver involvement would be consistent with § 164.510(b) of the HIPAA Privacy Rule as well as all other pertinent federal and state laws. We expect hospitals and CAHs to include the patient and the patient's caregiver/support person, where applicable, in the planning for a patient's post-discharge care. While it is

beneficial for providers to obtain the contact information for a patient's designated caregiver, we disagree with the commenter's recommendation to mandate such a requirement and believe that it would not be appropriate to require providers to make multiple attempts to contact caregivers during the discharge planning process. Such a requirement could prove to be burdensome to providers who are already compiling information for a discharge plan or discharge instructions and could potentially have the effect of hindering the discharge planning process. In addition, we do not believe that we should require hospitals to provide caregivers with the name and contact information for the staff at the hospital or CAH, as this may change over time. However, we note that as a best practice hospitals should give caregivers pertinent hospital contact information, so that caregiver can easily discuss concerns about the patient's discharge plan or instructions.

While we are not requiring providers to give a copy of the discharge plan to caregivers, patients can request a copy of their medical record, including the discharge plan, from the hospital, in their requested form and format, as required by newly revised § 482.13(d)(2) (as discussed below), and the hospital must comply with the patient's access request as required by the HIPAA Privacy Rule at 45 CFR 164.524. Similar requirements exist for HHAs and CAHs as well.

Comment: Several commenters submitted specific comments about the sub-regulatory interpretive guidance. Commenters recommended that CMS engage pertinent stakeholders early in an open and transparent process for developing the interpretive guidance, surveyor training, and provider education, and also implement a lean process improvement strategy.

Response: As with all regulations regarding the CoPs, the interpretive guidance will be updated once this final rule is published. The development of the interpretive guidance is a sub-regulatory process and is not required to be circulated for public comment. Comments regarding the process for developing the interpretive guidance and state survey and certification procedures are outside the scope of this final rule.

Comment: One commenter requested an extension to the 60-day comment period. Another commenter stated that the comment period was adequate.

Response: We believe that the 60-day comment period was sufficient, as evidenced by the number of comments we received. The comment period closed on January 4, 2016 for the Discharge Planning proposed rule, and on August 15, 2016 for the Hospital Innovation proposed rule.

Comment: A few commenters asked for clarification regarding provider reimbursement.

Response: Comments related to provider reimbursement are outside the scope of this final rule.

Comment: One commenter recommended that a patient's written notice of beneficiary's rights as an inpatient include a description of the patient's discharge rights. They also recommended that providers be required to provide patients with a discharge planning fact sheet. Another commenter recommended adding an additional section for hospitals, HHAs, and CAHs that would require these providers to advise patients of their rights to appeal a discharge or complain about the quality of care and advise the patient of the availability of assistance from Beneficiary and Family Centered Care Organizations. The commenters suggested referring to several CMS links regarding hospital appeals.

Response: The policies regarding a beneficiary's rights as an inpatient are outside the scope of this final rule. We continue to require providers to include patients and their caregiver/support persons in the discharge planning process. Additionally, the requirement at § 482.13(a)(2), under the Patient's Rights CoP for hospitals, requires the hospital to establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. Outside of the CoPs, other specific CMS requirements regarding the Medicare beneficiary appeals process may apply.

Comment: We received a large number of similar comments from individuals regarding patient nutrition and food security needs. Commenters recommended that the discharge planning requirements include a nutritional component and that specific language regarding food and nutritional services during the discharge planning process be included in the regulations.

Response: While we agree that a patient's nutrition and food security needs may impact care after discharge, we do not agree that including specific language regarding food and nutritional services during the discharge planning process is necessary for all patients as a minimum discharge planning requirement. We believe that mandating such additional requirements would be burdensome. However, we encourage providers to consider and address any patient food and drug interactions, as well as the patient's nutritional needs, as part of the necessary medical information that must go along with the patient as part of the discharge plan and which we are finalizing in this rule.

Comment: A few commenters offered recommendations regarding the use of certified health IT, EHRs, and "meaningful use" as described in our regulations at 42

CFR 495.22, and finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 37990, 38517). Some commenters focused on the development of a modular certification program for long-term and PAC providers, who were not eligible for meaningful use incentives under Medicare or Medicaid as authorized by the Health Information Technology for Economic and Clinical Health Act (HITECH Act). Additionally, commenters urged CMS and ONC to consider ways to encourage the adoption and use of these tools by rural and frontier providers to prevent a digital gap.

Another commenter recommended that the requirements in this rule align with current health IT certification requirements, in order to eliminate redundancy.

One commenter suggested that CMS require facilities that are electronically capturing information to do so using certified health IT.

Response: We did not propose the required use of certified health IT for health care providers under the CoPs. We also did not propose that providers use a specific form, format, or methodology for the communication of patient health care information. Therefore, these comments are out of scope of this rule. However, 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 and with patients. We also believe that health IT should be interoperable and that 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. Furthermore, we believe that facilities that are electronically capturing information should be exchanging that information electronically with providers who have the capacity to accept it.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). In addition, to further interoperability in post-acute care, CMS has launched the Data Element Library (DEL), which serves as a publicly available centralized, authoritative resource for standardized data elements and their associated mappings to health IT standards. The DEL furthers CMS' goal of data standardization and interoperability, which is also a goal of the IMPACT Act. These interoperable data elements can reduce provider burden by allowing the use and exchange of healthcare data, support provider exchange of electronic health information for care coordination, person-centered care, and support real-time, data driven, clinical decision making. Standards in the Data Element Library (https://del.cms.gov/) can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2019 Interoperability Standards Advisory (ISA) is available at https://protect2.fireeye.com/url?k=44af3763-18fa3e70-44af065c-0cc47adb5650-601d6acb74373f82&u=https://www.healthit.gov/isa.

We note that we work in conjunction with the Office of the National Coordinator for Health Information Technology (ONC), which acts as the principal federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of HHS, to promote these goals. As previously noted, ONC finalized the 2015 Edition final rule,

which sets out the current criteria for health IT to be certified under the ONC Health IT Certification Program. The 2015 Edition final rule facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. We note that CMS requires eligible hospitals and CAHs in the Medicare and Medicaid Promoting Interoperability Programs (previously known as the EHR Incentive Programs) and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to 2015 Edition health IT certification criteria beginning in CY 2019 (42 CFR 414.1305, 495.4, (81 FR 77538, 77555)). The 2015 Edition also defines a core set of data that health care providers have noted is critical to interoperable exchange and can be exchanged across a wide variety of other settings and use cases, known as the Common Clinical Data Set (C-CDS) (80 FR 62608 through 62702).

In an effort to continue to support seamless and secure access, exchange, and use of electronic health information, ONC published a proposed rule on March 4, 2019 in the **Federal Register**, titled "21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program" (84 FR 7424), which would implement certain provisions of the 21st Century Cures Act (the Cures Act) (Pub. L. 114-255), including conditions and maintenance of certification requirements for health information technology (health IT) developers under the ONC Health IT Certification Program (Program), the voluntary certification of health IT for use by pediatric health care providers, and reasonable and necessary activities that do not constitute information blocking.

The proposed rule would also modify the 2015 Edition health IT certification criteria and Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs. Specifically, the proposed rule builds on the Common Clinical Data Set with the U.S. Core Data for Interoperability (Version 1) (USCDI). The USCDI aims to support the goals set forth in the Cures Act by specifying a common set of data classes that will be required for interoperable exchange, and identifying a predictable, transparent, and collaborative process for achieving those goals (https://www.healthit.gov/isa/us-core-data-interoperability-uscdi).

Section 4003 of the Cures Act, enacted in 2016, and amending section 3001 of the Public Health Service Act (42 USC 300jj-11(c)), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC "…for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." A trusted exchange framework can allow for the secure exchange of electronic health information with, and use of electronic health information from other health IT without special effort on the part of the user. Trusted exchange networks allow for broader interoperability beyond one health system or point to point connections among payers, patients, and providers. Such networks establish rules of the road for interoperability, and with maturing technology, such networks are scaling interoperability and gathering momentum with participants,

including several federal agencies, EHR vendors, retail pharmacy chains, large provider associations, and others.

In light of the widespread adoption of EHRs, along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we solicited public comments on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the CoPs, the CfCs, and the requirements for Long Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers in the Request for Information published in our payment rules in 2018 in the **Federal Register**, titled "Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers". Specifically, we noted that CMS will consider revisions to the current CMS CoPs for hospitals such as: requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means, if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, we invited members of the public

to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We were particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcomed the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, and how revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers could play a role in addressing these barriers. We refer readers to the specific Request for Information sections in the following 2019 payment rules:

- FY 2019 Inpatient Prospective Payment System/Long Term Care Hospital Prospective Payment System Proposed Rule (83 FR 20550 through 20553);
- FY 2019 Inpatient Rehabilitation Facility Prospective Payment System Proposed Rule (83 FR 21004 through 21007);
- FY 2019 Hospice Wage Index and Payment Rate Update and Hospice Quality Reporting Requirements Proposed Rule (83 FR 20963 through 20966);
- FY 2019 Inpatient Psychiatric Facilities Prospective Payment System and Quality Reporting Updates Proposed Rule (83 FR 21135 through 21138);
- FY 2019 Prospective Payment System and Consolidated Billing for Skilled Nursing Facilities (SNF) Proposed Rule (83 FR 21089 through 21092);
- CY 2019 Home Health Proposed Rule (83 FR 32471 through 32473);

- CY 2019 End-Stage Renal Disease Prospective Payment System Proposed Rule (83 FR 34391 through 34394);
- CY 2019 Physician Fee Schedule Proposed Rule (83 FR 36006 through 36009); and
- CY 2019 Outpatient Prospective Payment System/Ambulatory Surgical Center Proposed Rule (83 FR 37209 through 37211).

We note that the comments we received on this Request for Information will be reviewed for informational purposes as we consider new or revised CoPs/CfCs/requirements for interoperability and electronic exchange of health information in future rulemaking.

Additionally, CMS published a proposed rule, which, if finalized as proposed, would improve interoperability and outline opportunities to make patient data more useful and transferable through open, secure, standardized, and machine-readable formats while reducing restrictive burdens on healthcare providers (84 FR 7610). Specifically, the proposed rule would revise the CoPs by requiring a hospital, psychiatric hospital, or CAH, which utilizes an EHR system with the capacity to generate information for patient event notifications (based on admission, discharge, and transfer (ADT) messages,) to demonstrate that its system's notification capacity is fully operational, is operating in accordance with all state and federal statutes and regulations regarding the exchange of patient health information, and utilizes a specified content exchange standard. Such patient event notifications would be required to include defined minimum patient health information, which were proposed to include the minimum patient health information (which must be patient name, treating practitioner name, sending institution name, and, if

not prohibited by other applicable law, patient diagnosis). Such messaging could be done directly, or through an intermediary that facilitates exchange of health information, and would occur at the time of admission and immediately prior to or at the time of discharge or transfer. And, in recognition of factors outside of a facility's control that may determine whether or not a notification can be successfully transmitted, an applicable hospital (as well as an applicable psychiatric hospital or CAH) would only be required to send ADT messages to licensed and qualified practitioners, other patient care team members and PAC services providers and suppliers (1) that receive the notification for treatment, care coordination, or quality improvement purposes; (2) that have an established care relationship with the patient relevant to his or her care; and (3) for whom the hospital (or psychiatric hospital or CAH) has a reasonable certainty of receipt of notifications.

Comment: One commenter stated that we should develop consistent standards of communication, information sharing, and discharge planning across the entire acute and post-acute care continuum. The commenter states that this consistency will facilitate standardization of the information collected and definitions used to improve the process, enhance communication, and ensure everyone is working toward the same goals.

Response: We agree that standardized methods of communication can be helpful to encourage consistency regarding compliance with this requirement. With regards to EHRs, we note that as of 2015, nearly all (96 percent) of non-federal acute care hospitals reported possessing a certified EHR system. Substantial adoption of certified health IT among hospitals is an important factor in moving the health care system towards common standards for sharing data. (ONC/American Hospital Association (AHA), AHA Annual

Survey Information Technology Supplement (http://dashboard.healthit.gov/evaluations/data-briefs/non-federal-acute-care-hospital-ehr-adoption-2008-2015.php.). We further believe that facilities, which are electronically capturing patient health care information, should be sharing that information electronically with health care providers that have the capacity to receive it to the extent they are authorized to do so.

Aside from the certification of EHR technology that was finalized in other rules, we did not propose standardized methods of communication and information sharing between different health care provider types as part of the Conditions of Participation.

Comment: A few commenters suggested adding pharmacists and occupational therapists to the discharge planning team. Another commenter suggested that we require hospitals, CAHs, and HHAs to consult with a "conflict-free community care coordinator" in developing the discharge plan and in identifying a list of HHAs, SNFs, IRFs, or LTCHs that are available to provide post-acute care.

Response: Our use of the broad term "practitioner" encompasses all practitioners, including non-physician practitioners, which may be operating within a hospital. Providers may utilize the appropriate practitioners that they believe will effectively conduct a patient's discharge planning process. For those reasons, the discharge planning CoPs do not include requirements specific to individual practitioner categories. The regulations text, as written, does not explicitly state who must provide the list of PAC providers to the patient or their representative. In addition, the regulation text does not prohibit hospitals from including any qualified personnel it chooses in this part of the discharge planning process. Typically, the list of PAC providers is given to patients or

their representative by a social worker or registered nurse (who is a case manager). The hospital must identify in its discharge planning policy the qualified personnel who will be involved in the discharge planning process and must execute their discharge planning process in accordance with their policies.

We appreciate the suggestion that providers utilize a conflict-free advisor. However, we believe that provider staff are capable of complying with the requirement to 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 utilization of contracted entities to perform this service would be a business decision of the provider, and it is not necessary to compel such business relationships via a regulatory requirement.

Comment: One commenter recommended that the discharge planning regulations be reviewed and updated more frequently.

Response: Although we frequently assess the need to update the CoPs, section 2(a) of the IMPACT Act, adding subsection 1899B(i) to the Act, requires us to update the CoPs and subsequent interpretive guidance for hospitals, CAHs, and PAC providers periodically, but not less frequently than once every 5 years.

B. Discharge Planning Requirements of the IMPACT Act of 2014 (Proposed § 482.43(c)(8), Proposed § 484.58(a)(6), and Proposed § 485.642(c)(8))

We proposed at § 482.43(c)(8), to require that hospitals assist patients, their families, or their caregivers/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 also proposed requirements for HHAs in accordance with the requirements of the IMPACT Act. For those patients who are transferred to another HHA or who are discharged to a SNF, IRF, or LTCH, we proposed at § 484.58(a)(6) 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.

As required by the IMPACT Act, HHAs must take into account data on quality measures and resource use measures during the discharge planning process. We also proposed at § 484.58(a)(6) 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. We received many public comments on these proposed requirements for HHAs and we refer readers to section II.C.4 of this final rule for a summary of those comments and our responses.

Finally, for CAHs, we proposed 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 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.

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 be required 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, we expect that CAHs 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. CAHs could also 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.

Comment: While many commenters supported the IMPACT Act's goals to standardize data amongst PAC providers, most commenters requested clarification on the specifics of the proposed IMPACT Act discharge planning requirements for hospitals,

HHAs, and CAHs. Most commenters asked CMS to clarify what data sources hospitals would be expected to use and where these data sources would be available. One commenter recommended that hospitals not assist patients in selecting a PAC provider or making decisions about the patient's post-acute needs, and instead require that access to these data be made available to patients and their families. A few commenters questioned the use of the Nursing Home Compare and Home Health Compare websites. These commenters were concerned that patients may receive inaccurate or outdated information. One of these commenters recommended that CMS provide a publicly available database of certified providers. One commenter stated that CMS's "Compare" websites can be confusing for patients and would likely require case management professionals to filter and interpret the data. The commenter further stated that additional studies would need to be conducted on how to disseminate this data in a manner that is easily understood and meets CLAS standards. The commenter therefore recommended that CMS provide standard, publicly-available data visualization and interpretation standards or guides. Additionally, another commenter recommended that CMS develop a patient resource to assist with the interpretation of the quality and resource use data. Another commenter noted that while quality data is available through the Nursing Home and Home Health Compares, similar websites do not exist for other PAC providers, such as IRFs.

Several commenters questioned whether relevant hospital practitioners were qualified to interpret, discuss, and answer questions about the quality and resource use data. A few commenters recommended that CMS give providers more information and guidelines on how to discuss PAC data on quality measures and data on resource use

measures with patients. In particular, the commenters stated that CMS should provide concise, consumer-friendly information on each measure and how to evaluate the performance of a specific measure to determine whether a certain provider is appropriate for a patient. Another commenter asked that the final rule acknowledge that it may not be feasible for a hospital to provide complex quality data for each PAC facility that is being considered with the expectation that the hospital explain all of the nuances that account for different ratings.

Response: Section 1899B(i) of the Act requires that PAC providers, hospitals and CAHs take into account quality, resource use, and other measures in the discharge planning process. We understand that commenters had concerns about using appropriate data that would be comparable to the data that would be gathered and provided in accordance with the requirements of the IMPACT Act. However we note that since the publication of the proposed rule in 2015, the measures we implemented into the PAC Quality Reporting Program (QRPs) for the domains of functional status, skin integrity, the incidence of major falls, and the resource use and other measures as required by the Act are now publicly available on the IRF, SNF, LTCH, and Home Health (HH) Compare websites. Data from these measures are now being reported to providers by means of private provider feedback reports. Other data as required by the IMPACT Act will be publicly available in the near future. We therefore expect providers to make reasonable efforts to use the quality and resource use measure data that are currently available to them until all of the measures stipulated in the IMPACT Act are finalized and publicly reported. Additional explanations, resources, instructions, and help on how to use the IRF Compare, HH Compare, Nursing Home Compare, and Long-Term Care

Hospital Compare websites are currently available on the following pertinent websites:

- https://www.medicare.gov/inpatientrehabilitationfacilitycompare/.
- https://www.medicare.gov/homehealthcompare/search.html.
- https://www.medicare.gov/nursinghomecompare/search.html.
- https://www.medicare.gov/longtermcarehospitalcompare/.

While the data from these sources are not available in "real time," the data are posted as soon as feasible. Providers should use these data sources to assist patients as they choose a PAC provider that aligns with the patient's goals of care and treatment preferences, and we would also expect providers to document all efforts regarding this requirement in the patient's medical record.

We believe that providers have the ability and knowledge to interpret and discuss the publicly available data on quality and resource use measures at the most basic levels. We note that we do not expect providers to give overly detailed and complex analyses of the quality and resource use data, which may only serve to confuse patients and/or their caregivers, nor do we expect providers to attempt to provide patients and their caregivers with data that do not exist regarding PAC facilities. We expect providers to put forth their best effort to answer patient questions regarding the data. We also encourage providers to refer to www.medicare.gov for additional resources and help. Further information regarding specific measures mandated by the IMPACT Act will be available in forthcoming regulations. Finally, we also encourage providers to consult the sub-regulatory interpretive guidance that will be available after publication of the final rule.

Comment: Several commenters asked for clarification on what additional information can be provided to patients about PAC providers. A few commenters gave

examples of marketing materials, other information the provider may have regarding a PAC's quality and resource use, whether the patient's health insurance covers the patient's specific PAC provider choice, and information regarding out of pocket cost for PAC providers.

Response: Providers can use additional available information to assist patients as they select a PAC provider, so long as the information presented aligns with the patient's goals of care and treatment preferences. The IMPACT Act in no way limits providers' ability to augment the information provided to patients. All attempts to assist patients should be documented in the medical record.

Furthermore, these discharge planning requirements do not prohibit providers from giving patients information regarding coverage of a selected PAC by the patient's insurance or specifics on out of pocket costs for PAC providers. Providers may give this information to patients if they choose. However, we do not expect providers to have definitive knowledge of the terms of a patient's insurance coverage or eligibility for post-acute care, or for Medicaid coverage, but we encourage providers to be generally aware of the patient's insurance status. We do not believe that it is appropriate to mandate such a requirement here, as these CoPs provide basic requirements for the discharge planning process.

Comment: Several commenters asked for clarification on how providers can assist patients in choosing a PAC provider without improperly steering the patient to certain providers. Some commenters expressed concern that the proposed requirements may lead to hospital steering, with some commenters expressing concern that certain hospitals may employ tactics to purposely channel patients to other providers or suppliers

within their medical system or under common ownership. A few commenters questioned whether patient choice would be influenced by the patient receiving services or care from a Medicare fee-for-service provider who may be participating in an alternative payment model, such as bundled payment programs, shared savings programs, or full clinical and financial risk payment programs.

Commenters expressed their belief that CMS should allow providers to identify the best PAC providers that lead to improved efficiency and better outcomes, so long as patients are given the ultimate choice of PAC provider and all financial dealings and conflicts of interest are disclosed to the patient during the discharge planning process.

Response: We understand the commenter's concerns regarding patient steering. However, we believe compliance with the revised CoP and the fraud and abuse laws, including the physician self-referral law and Federal anti-kickback statute, is achievable. We believe that hospitals, HHAs and CAHs will be in compliance with this requirement if they present objective data on quality and resource use measures specifically applicable to the patient's goals of care and treatment preferences, taking care to include data on all available PAC providers, and allowing patients and/or their caregivers the freedom to select a PAC provider of their choice. Providers will have to document all such interactions in the medical record. In addition, we expect hospitals to comply with the requirements in § 482.43(c) and inform the patient and/or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services, while not specifying or otherwise limiting the qualified providers or suppliers that are available to the patient. Hospitals, HHAs, and CAHs that have concerns that providing objective information in these circumstances may conflict with

other laws can obtain guidance on the physician self-referral law at www.cms.gov/physicianselfreferral and on the Federal anti-kickback statute at www.oig.hhs.gov. Information about obtaining advisory opinions regarding the application of the physician self-referral law in specific circumstances can be found at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html and regarding the application of the anti-kickback law at https://oig.hhs.gov/compliance/advisory-opinions/index.asp.

We remind providers that compliance with these requirements will be assessed through on-site surveys by CMS, state survey agencies, and AOs and that purposeful patient steering (that is, directing patients and/or their caregivers to PAC providers that do not align with the patient's goals of care and treatment preferences) could lead to a determination of provider noncompliance with the requirements in this rule. We also note that physician self-referral violations may result in imposition of penalties set out under section 1877(g) of the Act.

Comment: One commenter questioned the guidance on resource use measures in the proposed rule with regards to dementia patients. The commenter stated that data on discharge to the community and data on preventable readmission rates for persons with dementia is limited. The commenter further stated that CMS could collect data on how many all-cause readmission beneficiaries have dementia.

Response: Providers must use and share data on quality measures and data on resource use measures that are relevant and applicable to the patient's goals of care and treatment preferences. While we believe that resource use data can be helpful to all patients, providers can tailor the specific data that are given to patients so that the data are

applicable to the patient's specific medical condition or circumstance. The provider should ensure that the data given to patients aligns with the patient's ultimate goals of care and treatment preferences.

The comments regarding the collection of quality measures are outside the scope of this final rule. However, we do appreciate the commenter's suggestion regarding data that pertain to patients with dementia.

Comment: One commenter asked that CMS clarify the protocols that providers would be expected to follow if a patient refused to agree to be discharged to a PAC facility chosen on the basis of the supplied quality data and/or family preferences, especially when no other safe options existed in the area.

Response: We expect hospitals, HHAs, and CAHs to document the patient's refusal in the medical records and continue to make reasonable efforts to work with the patient and/or the patient's caregiver to find appropriate substitutions. However, we note that Medicare and Medicaid participating facilities are surveyed regularly to assure quality, and we believe that Medicare facilities in good standing can be trusted to provide services safely.

Final Decision: After consideration of the comments we received on the Discharge Planning proposed rule, we are finalizing and redesignating the proposed requirements at §§ 482.43(c)(8) and 485.642(c)(8) as §§ 482.43(a)(8) and 485.642(a)(8), respectively, without modification. We are finalizing and redesignating the requirements in proposed § 484.58(a)(6) as § 484.58(a), without modification.

C. Implementation

We solicited comments on the timeline for implementation of the discharge planning requirements for HHAs and CAHs. We received many comments in response to this solicitation for comments and recommendations on the effective date and the date of implementation of the discharge planning requirements in hospitals.

Comment: Many commenters recommended a delay in the implementation or the effective date of the final discharge planning requirements for all providers. Most of these commenters noted that the proposed discharge planning requirements were extensive and that hospitals, HHAs, and CAHs would need additional time to understand and fully implement all the requirements, train staff, and update EHR systems to reflect the final discharge planning requirements. Recommendations for implementation timeframes or delays in the effective date included:

- 1 to 5 years, with several commenters specifically recommending a 1-year delay;
- Piloting discharge planning requirements before finalizing them;
- Phasing in the requirements; and
- A 2-year delay with implementation to begin with inpatients that hospitals determine are most at risk for readmission.

Many commenters were particularly concerned about the effective date for certain specific proposed requirements. Most suggested delaying the effective date for the discharge planning requirements of the IMPACT Act until quality reporting data is publicly available.

Response: We continue to believe that most hospitals and CAHs have discharge planning processes in place and that these providers will be well prepared to implement

the final discharge planning requirements. In addition, we are either revising or not finalizing most of our proposed discharge planning requirements, such as the design, applicability, and timeframe requirements for hospitals and CAHs, which will reduce additional burden. Therefore, we do not believe an additional delay in the effective date for hospitals and CAHs is necessary. In light of the significant streamlining of the final discharge planning requirements for HHAs, we do not believe an additional delay in the effective date for implementation of the final discharge planning requirements for HHAs, including the Impact Act requirements at § 484.58(a) are necessary. We also believe the discharge planning requirements in this final rule are beneficial to patients and their caregivers (where applicable) and will reduce patient readmission risks and improve patient care. We refer readers to the provider-specific sections II.C through II.E of this final rule, for a summary of the public comments we received, our responses to the comments, and the final requirements and to section II.B of this final rule for a discussion of the discharge planning requirements of the IMPACT Act and the measures that are currently publicly available.

Final Decision: After consideration of the comments received, we are requiring implementation of the final requirements for HHAs 60 days after date of publication of this final rule, including the IMPACT Act requirements at § 484.58(a). Hospitals and CAHs will be required to comply with all of the final requirements 60 days after date of publication of this final rule.

D. Prescription Drug Monitoring Programs (PDMPs)

In the Discharge Planning proposed rule, we encouraged providers to consider using their state's Prescription Drug Monitoring Program (PDMP) during the evaluation

of a patient's relevant co-morbidities and past medical and surgical history (80 FR 68132). Given the potential benefits of PDMPs as well as some of the challenges noted in the proposed rule, we solicited 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. We also solicited comments on the use of PDMPs in the medication reconciliation process.

Comment: We received a large number of comments in response to our solicitation for comments on the use of PDMPs during the discharge planning process. A majority of commenters strongly disagreed with establishing a requirement for providers to consult with their state's PDMP, with most stating that such a requirement would be burdensome and time consuming for providers and their prescribing practitioners during the discharge planning process. A few commenters expressed specific concerns about the burden of such a requirement on CAH providers. One commenter expressed concern about the applicability of this requirement to pediatric patients and recommended that this requirement be optional for pediatric patients under the age of 12. Many commenters agreed that PDMPs could potentially be useful, if the many challenges that currently exist within the PDMP systems are resolved. In addition, some commenters stated that PDMPs could work if there were a national or standardized PMDP database. In addition, one commenter requested clarification on how CMS expects providers to use PDMPs.

Several commenters agreed that many PDMPs still encounter legal, policy, and technical challenges. Many of these commenters raised issues of interoperability and noted that access to PDMPs varies widely by state and that data contained within their individual state's PDMP is often incomplete or out of date or provides limited access or

access that is slow. Some commenters explained that there are additional challenges for providers whose patients cross multiple state lines, since PDMPs vary by state. One commenter questioned whether these hospitals would be required to check all state databases that are in their surrounding area.

Some commenters noted that their state did not have a PDMP. Other commenters noted that the proposed requirement would conflict with some state laws and requirements. These commenters indicated that state PDMP statutes were not enacted to assist discharge planning. A few commenters recommended deferring to the local state requirements while others specified the importance of addressing restrictions under the HIPAA Privacy Rule at §164.510. A few commenters gave the example of Ohio as a state with a mandatory PDMP requirement. Ohio currently requires prescribing physicians and other prescribing practitioners to check the Ohio Automated Rx Reporting System (OARRS). One commenter recommended that CMS work with state PDMP programs to facilitate proactive PDMP report generation that could be sent to hospitals at the time of patient admission.

Some commenters stated that HHAs in their state do not have access to their state's PDMP system; and that only pharmacists, prescribers, and law enforcement officials have access to the system. Other commenters noted that HHAs do not prescribe controlled substances or other types of medications.

A few commenters agreed with requiring providers to use PDMPs. Some other commenters supported CMS' continued encouragement of the use of PDMPs, but encouraged CMS not to mandate the use of PDMPs. One commenter stated that a mandatory requirement should not be instituted for providers; instead, each facility

should be able to determine whether use of the PDMP is appropriate or necessary on an individual patient level. One commenter stated that PDMPs should only apply to the prescription of controlled substances until the universal use of PDMPs is better understood.

Response: We thank the commenters for their feedback. We received many comments that stated that we had proposed PDMP requirements for providers and many of these comments recommended that we not finalize, or delay finalization, of this proposal. However, we clarify that we did not propose PDMP requirements, and solely solicited comments in the proposed rule on whether provider consultations with PDMPs during the discharge planning process should be required.

Final Decision: After taking into consideration the comments received in response to our solicitation of comments for PDMPs, we agree that it would be difficult to implement a mandatory requirement for providers to access their state's PDMP during the discharge planning process at this time. We appreciate stakeholder input on this issue. We will not require that hospitals, including LTCHs and IRFs, HHAs or CAHs 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, nor will we require providers to use or access PDMPs during the medication reconciliation process. However, as discussed in the proposed rule, we strongly encourage practitioners to utilize strategies and tools, such as PDMPs, to the extent permissible under the HIPAA Privacy Rule and state law, to help to reduce prescription drug misuse. Furthermore, we note that there may be state laws that require practitioners to consult with their state's PDMP system and we acknowledge that since the publication of the proposed rule,

additional states have adopted statewide PDMP programs. We therefore remind providers that they must continue to abide by all applicable state laws.

E. Patients' Rights and Discharge Planning in Hospitals

1. Patient's Access to Medical Records (Proposed § 482.13(d)(2))

In the Hospital Innovation proposed rule, we proposed clarifying the requirement for hospitals at § 482.13(d)(2) to state that the patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, within a reasonable time frame (81 FR 39475). We also note that our use of terms "patients" and "medical records" instead of the HIPAA-defined terms "individual," "protected health information," and "designated record set" is not intended to suggest a different standard for covered entities subject to the HIPAA Privacy Rule. (See 45 CFR 164.524). We simply are using well-understood terms that are consistent across all of our regulations. The Office for Civil Rights recently issued Frequently asked Questions document about medical records access clarifying that the requirement to send medical records to the individual is within 30 days (or 60 days if an extension is applicable) after receiving the request, "however, in most cases, it is expected that the use of technology will enable the covered entity to fulfill the individual's request in far fewer than 30 days."

(See http://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/#newlyreleasedfaqs.) Individuals who have not

been provided with their medical records within the 30-day timeframe required by HIPAA or who experience other difficulties accessing their medical records can file a complaint with Office for Civil Rights at: http://www.hhs.gov/hipaa/filing-a-complaint/index.html. We also refer the public to the following information pertaining to the Promoting Interoperability Program (formerly known as the EHR Incentive Program) and to an individual's rights under HIPAA to access their health information at the following websites: https://www.hhs.gov/hipaa/for-professionals/faq/2051/under-the-ehr-incentive-program-participating-providers/index.html and https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/index.html.

Comment: Commenters were generally supportive of this proposal. Some commenters suggested allowing hospitals to provide to the patient copies of their medical record in the format that the facility deems appropriate at the time of the request if the patient has not specified a format for receiving the records. One commenter recommended that the regulation specify that discharge planning documents be immediately accessible to patients and their caregivers. The commenter notes that under the current medical record requirement (most likely the commenter is referring to § 482.24), it is difficult for caregivers to obtain a medical record from a hospital until after discharge, even with the patient's signed consent.

Response: This final rule states that the patient has the right to access their medical records in the form and format they request, if it is readily producible in such form and format. The medical record must include any discharge planning documents, so it is not necessary for this requirement to specify any specific part of the medical record as requested by the commenter. Patients are free to request their entire medical record or

a specific portion of it if they choose, including any discharge planning documents, as noted by the commenter. However, these documents (and, by extension, the entire medical record) would obviously not be complete until after a patient is discharged. Further, the provision goes on to state that if the records are not readily producible in the form or format requested by the patient, the hospital must provide the records in a readable hard copy form or such other form and format as agreed to by the facility and the individual. We encourage hospitals to communicate with the patient to determine in which format they would prefer to receive the records; however, if no format is requested, the hospital has the flexibility to provide the records in a readable hard copy form.

Final Decision: After consideration of the comments we received on this proposal for the Hospital Innovation proposed rule, we are finalizing § 482.13(d)(2) with two minor editorial modifications.

We are moving the phrase "including current medical records" to a more appropriate place in the text, that is, immediately following the opening language of the provision, "The patient has the right to access their medical records," so that it now reads, "The patient has the right to access their medical records, including current medical records… "

In the proposed rule, we had awkwardly and inadvertently placed the phrase further along so it stated that the patient has the right to access their medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard

copy form or such other form and format as agreed to by the facility and the individual, *including current medical records*, within a reasonable time frame.

In removing the phrase from where it was proposed in the regulatory text, we have also added the word, "and" to precede the phrase, "within a reasonable time frame," so that it now more appropriately reads, "…*and* within a reasonable time frame."

2. Conditions of Participation (CoP)--Discharge Planning (Proposed § 482.43)

We proposed to revise the existing requirements in the form of 6 standards at § 482.43. The most notable proposed revision was to require that all inpatients and specific categories of outpatients be evaluated for their discharge needs and have a written discharge plan developed. We proposed to retain many of the current discharge planning concepts and requirements, but proposed to revise them to provide more clarity and to place emphasis on the development of each patient's individual discharge plan as opposed to the burdensome, current requirements that place more emphasis on the evaluations to determine which patients need discharge plans. We also proposed to require specific discharge instructions for all patients.

We proposed to continue our efforts to reduce unnecessary and costly 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 persons (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 proposed at § 482.43, Discharge planning introductory paragraph, to require that a hospital have an effective discharge planning process that focuses on the patients' 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.

Our proposed hospital regulatory requirements were the basis for all other proposed discharge planning requirements as set out in the proposed rule. Since application of the proposed regulatory language for hospitals might be burdensome for CAHs and HHAs, we tailored specific proposed requirements to each providers' and suppliers' unique situation.

Many commenters remarked on the proposed discharge planning regulations for hospitals, but indicated that their comments could also be applied to CAHs. Therefore, where appropriate, we included CAHs in this section of the final rule.

Comment: Most commenters strongly supported a person-centered approach that places the patient at the center of the discharge planning process by requiring hospitals to develop and implement a discharge planning process that focuses on the patient's goals and preferences. Several of these commenters expressed concern that these proposed discharge planning requirements were unclear.

Response: We thank the commenters for their feedback regarding a person-centered approach to discharge planning. We continue to believe that hospitals should take into consideration a patient's goals of care and treatment preferences and we note

that person-centered care is particularly important when patients are discharged to home or to community-based services. In response to the public comments that we received that expressed concern about the clarity of the proposed discharge planning requirements, we have revised the wording of the requirements. Specifically, we are finalizing the discharge planning introductory paragraph with minor changes in § 482.43, and we are continuing to emphasize the importance of the consideration of the patient's goals of care and treatment preferences during the discharge planning process and within the discharge plan. As we discuss in detail in the subsequent sections of this final rule, we also align, where appropriate, and as informed by the public comments, our final discharge planning requirements for hospitals (and CAHs) with the mandates in section 1861(ee)(1) of the Act.

Final Decision: After consideration of the comments we received on the proposed rule, we are finalizing the first sentence in the introductory paragraph of § 482.43 with minor modifications, to state that the hospital must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to preventable hospital readmissions. The remaining language for the introductory paragraph remains the same.

3. Design (Proposed § 482.43(a))

We proposed to establish a new standard, at § 482.43(a), "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 proposed 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.

Comment: A number of commenters approved of the proposed new standard at § 482.43(a), including one commenter that noted that physician involvement in the design of a hospital's discharge policies and procedures is essential to its success. Several commenters submitted comments questioning the proposed requirements regarding the role of the governing body, medical staff, and relevant departments in relationship to developing the discharge planning process, and suggested that the final regulations be much less prescriptive regarding these roles. One commenter questioned the practical enforceability of the requirement for a hospital to have its discharge planning process in writing and approved by the hospital's governing body. Many commenters made suggestions for additions of specific disciplines and entities to be consulted when developing the discharge planning process. One comment suggested that hospitals and CAHs should be required to use a risk-stratification approach (that is, an approach for identifying and predicting which patients are at high risk, or likely to be at high risk, and prioritizing the management of their care in order to prevent worse outcomes) among the elements of a hospital's discharge planning policies and procedures. Another commenter suggested that there should be a requirement for performance metrics as part of the

design of a discharge process so as to inform formative assessment of policies, plans, and procedures, and their success or need for change. Still other commenters recommended that CMS not be overly prescriptive in the proposed design of the discharge planning process, and recommended that CMS put forward a design approach that would allow for customization based on patient needs. However, most commenters who made suggestions related to this section expressed concern about the burden of the proposed design requirement and whether those burdens outweighed any potential, though not proven, benefits of the requirements.

Response: Based on the comments that we received, we agree with commenters who stated that this proposal was too process-oriented and too prescriptive. Further, we believe that any additional requirements added to this section would make the discharge planning requirements even more prescriptive and burdensome, which would not reflect the concerns expressed by the majority of commenters. We therefore are not finalizing the requirements in § 482.43(a). Hospitals and CAHs may choose to include any of the factors that we originally proposed, as well as those described by commenters, in designing their discharge planning process. We encourage hospitals and CAHs to consider performance metrics when designing their discharge processes. We also encourage the use of performance metrics for hospitals when they reassess their discharge planning processes on a regular basis and urge hospitals to consider including these reassessments as projects within their Quality Assessment and Performance Improvement (QAPI) programs.

Comment: Several commenters recommended that CMS require hospitals to review their discharge planning processes every 2 years.

Response: We continue to believe that hospitals and CAHs should assess their discharge planning processes on a regular basis. However, we believe that it is not appropriate, and is in fact unduly burdensome, to establish a specific timeframe for this review. We believe that each hospital and CAH should have the flexibility to establish its own timeframe for periodic review. While we are not establishing a specific timeframe requirement in order to preserve flexibility for hospitals and CAHs, we would recommend that a hospital or CAH to do its periodic review every 2 years at a minimum. In addition, hospitals and CAHs would still have the flexibility to perform this review more frequently than every 2 years if they wish to do so.

We therefore are finalizing a provision at § 482.43(a)(7) (as originally proposed at § 482.43(c)(10)) that would require a hospital (or a CAH) to assess its discharge planning process on a regular basis, which would 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.

Comment: One commenter recommended that the final rule include an explicit requirement that a hospital's discharge policies and procedures accommodate the needs of patients whose primary language is not English.

Response: As we noted previously, and in order to encourage patient engagement and understanding of their discharge plan or instructions, we recommend providers follow the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care

(https://www.thinkculturalhealth.hhs.gov/clas/standards), which provide guidance on providing instructions in a culturally and linguistically appropriate manner.

Final Decision: After consideration of the comments we received on the proposed rule, we are not finalizing the proposed design requirements at § 482.43(a).

4. Applicability (Proposed § 482.43(b))

We proposed to revise the current requirement (§ 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 proposed to 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 (since these patients are often kept in the hospital overnight), 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 thought at the time that the aforementioned categories of patients would benefit from an evaluation of their discharge needs and the development of a written discharge plan.

Comment: While a number of commenters agreed with the proposal to broaden the categories of patients who would be evaluated for post-discharge need, stating that they believed the inclusion of these categories of patients was necessary for effective transition from acute settings to post-acute settings, the majority of commenters expressed concern over the undue burden that they believe would result from this

proposed change, particularly for small and rural hospitals. Many stated that they believe that the current evaluation requirement is effective for screening and targeting high-risk patients who have true discharge needs. A number of commenters stated that they already routinely screen certain categories of outpatients, such as observation patients, and that automatically requiring discharge plans for patients in these categories would shift resources away from those patients most in need of discharge plan.

Response: We agree with commenters that the requirement needs to be scaled back in its scope and applicability to a more flexible requirement. We also agree that the proposed requirement could potentially have the unintended consequence of shifting hospital resources away from those patients most in need of a discharge plan. Finally, we agree with commenters that a discharge planning evaluation and screening of patients who have discharge needs is a more appropriate approach to selecting patients for establishing a discharge evaluation. We therefore are not finalizing the requirements at proposed § 482.43(b). Instead, we are finalizing requirements at § 482.43(a) introductory text and (a)(2), respectively, that would require that a hospital's discharge planning process must identify, at an early stage of hospitalization (ideally when the patient is admitted as an inpatient, or shortly thereafter), those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified, as well as for other patients upon the request of the patient, patient's representative, or patient's physician. In addition, at § 482.43(a)(2), a discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-hospital

extended care services, and home health services, and must also determine the availability of those services.

The regulatory flexibility and framework of these final requirements will allow each hospital to establish and tailor its own policy parameters for discharge planning evaluations according to its specific patient populations, individual institutional needs and resources, and own medical staff recommendations as long as the policies and procedures established and implemented meet or exceed the requirements finalized in this rule.

Final Decision: After consideration of the comments we received on the proposed rule, we are revising proposed § 482.43(b), to be finalized as § 482.43(a) introductory text and (a)(2), to require that the hospital's discharge planning process identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning, and must provide a discharge planning evaluation for those patients so identified, as well as for other patients upon the request of the patient, patient's representative, or patient's physician. A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-hospital extended care services, and home health services; such evaluation must also determine the availability of those services.

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

We proposed 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). We proposed to require that the discharge plan be tailored to the unique goals, preferences, and needs of the patient. We proposed 10 specific elements to be addressed in the discharge planning process as follows:

- Proposed § 482.43(c)(1): We proposed that an RN, 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.
- Proposed § 482.43(c)(2): We proposed to require that a hospital must 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.
- Proposed § 482.43(c)(3): We proposed to retain and clarify the current requirement at § 482.43(c)(4), regarding reassessment of the plan as necessary. We also proposed to require that the hospital's discharge planning process ensure an ongoing patient evaluation throughout the patient's hospital stay or visit in order to identify any changes in the patient's condition that would require modifications to the discharge plan.
- Proposed § 482.43(c)(4): We proposed 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.

- Proposed § 482.43(c)(5): We proposed 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. We proposed that hospitals consider the patient's or caregiver's capability and availability to provide the necessary post hospital care. We proposed that hospitals consider the availability of, and access to, non-health care services for patients. We proposed that hospitals 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.
- Proposed § 482.43(c)(6): We proposed a new requirement 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.

- Proposed § 482.43(c)(7): We proposed a new requirement that the patient's discharge plan address the patient's goals of care and treatment preferences.
- Proposed § 482.43(c)(8): We proposed that the hospital assist patients and their families in selecting a post-acute care provider by using and sharing data on quality measures and data on resource use measures as is relevant and applicable to the patient's goals of care and treatment preferences.
- Proposed § 482.43(c)(9): We proposed to 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 could be made before discharge.
- Proposed § 482.43(c)(10): We proposed to require hospitals to assess their discharge planning processes on a regular basis, including 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.

Comment: Numerous commenters expressed overall disagreement with the overly detailed, prescriptive nature of the proposed requirements. While they supported the overall goal of improving discharge planning, commenters expressed concern about stifling innovation, interfering with patient-provider relationships, overburdening discharge planning staff, and diverting patient care resources to regulatory process requirements.

Response: We are sensitive to the concerns expressed by commenters, as we share their goal of streamlining the regulations to balance the need for minimum health and safety requirements with the need for maximum hospital flexibility to achieve patient

outcomes. In light of the concerns expressed by commenters, we have significantly revised the proposed requirements to focus less on specific processes and prescriptive elements, and more on overall outcomes and flexibilities. We have also reorganized and simplified the regulatory requirements (such as those originally proposed in § 482.43(c)(9) and (10)), where appropriate, to improve their clarity and understandability.

Comment: A small number of commenters recommended that we mandate that nurses with training and experience in rehabilitation, as well as respiratory therapists, be involved in the discharge needs evaluation and in the development of the discharge plan.

Response: We do not believe that it is appropriate to require hospitals to use certain specialty practitioners in any particular step of the discharge planning process. However, hospitals are not precluded from doing so. We believe that the requirements should allow hospitals to determine what is appropriate for its patient population and its facility in such circumstances.

Comment: The majority of commenters opposed the establishment of a specific timeframe of 24 hours after admission or registration for beginning to identify anticipated discharge needs for each applicable patient (proposed § 482.43(c)(2)). Some commenters noted that applying a 24-hour requirement, without consideration of patient need, could result in a waste of valuable hospital resources or inaccurate conclusions.

Response: We agree with commenters that setting rigid time frames may not take into account the facts and circumstances of a particular patient's care; therefore, we are removing this proposed requirement from this final rule.

Comment: Several commenters supported our proposal to require that the hospital's discharge planning process require a regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan and that the discharge plan be updated, as needed, to reflect these changes. However, one commenter asserted that this requirement is redundant, as it is already included in the regular course of care for patients. Another commenter supported the proposed requirement and noted that the needs of patients with dementia and their caregivers evolve frequently.

Response: We continue to believe in the importance of requiring that hospital's discharge planning process require a regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan and that the discharge plan be updated, as needed, to reflect these changes. 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). We are finalizing the requirement from proposed § 482.43(c)(3) with modifications at § 482.43(a)(6) in this final rule to 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. We note that these requirements would allow for hospitals to consider the specific needs of patients with dementia.

Comment: One commenter requested that the interpretive guidance not impose a burdensome documentation requirement for hospitals when conducting the re-evaluation of a patient's discharge needs.

Response: The interpretive guidance is developed in accordance with the CoP regulations. Therefore, while the interpretive guidance will further clarify the CoPs, they will not impose additional requirements beyond those in the CoPs.

Comment: A few commenters requested clarification on the definition of "the practitioner responsible for the care of the patient" in the proposed requirement 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. The commenter asked whether the practitioner will always be a hospital-based provider or the patient's personal physician. One commenter noted that this requirement would be difficult to complete for a medically complex patient with multisystem involvement. One commenter opposed the inclusion of this requirement in the CoPs for hospitals on the basis that hospitals do not control practitioner-patient interaction. The commenter also noted the absence of an explanation regarding the language stating that a practitioner should be "involved in" the process.

Response: We agree that the proposed requirement does not allow for flexibility for hospitals, CAHs, and practitioners, especially for multi-facility providers that treat medically complex patients. Taking into account the concerns that we have received on this proposal, we are not finalizing the proposed requirements in § 482.43(c)(4).

Comment: Many commenters supported the proposed requirement for hospitals to consider certain criteria while evaluating a patient's discharge needs, specifically highlighting proposals related to psychiatric and behavioral health needs, and non-medical needs and support services. Some commenters suggested that hospitals should

be required to inform patients and their caregivers of their right to receive post-acute care in their home or a community setting, as is appropriate for the patient's care and needs, so long as the placement can be reasonably accommodated. One commenter recommended that hospitals review a patient's need for the use of technology and whether or not technology is necessary to maintain a patient's health and safety or individual goals. A few commenters recommended specific revisions to the proposed requirement that the hospital consider the availability of caregivers and community-based care for each patient, including recommendations such as requiring hospitals to consider a patient's socioeconomic condition when identifying and evaluating a patient's anticipated post-discharge needs, and consider patient eligibility for Program of All-Inclusive Care for the Elderly (PACE) and services through the Veterans Administration.

However, other commenters stated that the proposed requirements that a hospital must consider in evaluating a patient's discharge needs are overly prescriptive and overly detailed. A few commenters stated that a requirement to consider a patient's access to non-health care services and community-based care providers would be burdensome for hospitals. One commenter stated that while these services may benefit the patient, hospitals cannot be expected to provide an exhaustive list of services and that the hospital has limited reliable methods to identify non-health care resources in the community.

One commenter disagreed with the use of the term "consider" in the proposed requirement, stating that using the term "consider" may cause interpretation differences when surveying for compliance. The commenter recommended that CMS clarify that discharge plans can vary, depending on the patient, and that in many cases a patient's discharge instructions could constitute a "discharge plan." The commenter also

recommended that CMS coordinate with AOs to develop mutually agreed upon interpretive guidelines, which all surveyors would use when assessing compliance with this provision.

Response: We agree that the proposed list could be burdensome, and, therefore, we are not finalizing it in this final rule. We are instead finalizing a requirement at § 482.43(a)(2) that a discharge planning evaluation include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-hospital extended care services, home health services, and non-health care services and community based care providers, and that the evaluation must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

We acknowledge that patients and families seeking post-hospital non-health care services, as well as the discharge planning staff of hospitals assisting them with this process, frequently find themselves confronted with what can be an overwhelming number of organizations and requirements. This search occurs at a time of vulnerability or crisis, and can result in patients, families, and caregivers making decisions based on incomplete, and sometimes inaccurate, information about their options. In partnership with the Veterans Health Administration and the Administration for Community Living (ACL) within HHS, CMS is working collaboratively with states to streamline access to long-term services and supports (LTSS) through a network of organizations, including Aging & Disability Resource Centers (ADRCs), Area Agencies on Aging (AAAs), and Centers for Independent Living (CILs)) that make up a statewide No Wrong Door (NWD) system. We expect that CILs, AAAs, and ADRCs would assist patients in

accessing LTSS, and would have staff trained to help patients and their families exercise their choice and control over the types of LTSS that work best for them in their lives. Along with the U.S. Department of Veterans Affairs, CMS formally recognized the importance of state ADRC/NWD systems by publishing the NWD System Medicaid Administrative Guidance (https://www.medicaid.gov/medicaid/financing-and-reimbursement/downloads/no-wrong-door-guidance.pdf) and the "Expanded Access to Non-VA Care Through the Veterans Choice Program Rule" interim final rule (80 FR 674991, December 1, 2015.)

We therefore urge hospitals to develop collaborative partnerships with these community based care organizations in their respective areas to improve transitions of care that might support better patient outcomes. Regarding hospital expectations, hospitals are required to comply with all applicable Federal laws, including the Americans with Disabilities Act (ADA). It is our expectation that hospitals would administer their services, programs, and activities in the most integrated setting appropriate to individuals with disabilities, in compliance with the ADA. For further information on ADA compliance, we recommend that readers visit https://www.ada.gov/. For further information about other nondiscrimination laws see http://www.hhs.gov/civil-rights. We expect hospitals to develop collaborative relationships with their area and state ADRCs, AAAs, and CILs that are knowledgeable of the availability of these services in the community and would be able to help connect patients as well as their families, friends, and caregivers to these resources. We would also expect that these hospital efforts to collaborate and to connect patients with these types of community-based care organizations will be documented in the medical record. It is for this reason

that we urge hospitals to develop ongoing and collaborative partnerships with ADRCs, AAAs, and CILs. We remind hospitals that they can find more information on community-based services and community-based organizations at http://www.acl.gov/.

Considerations must also be made for those patients whose personal homes have been adversely impacted due to an emergency or disaster. We note that the Emergency Preparedness final rule requires health care facilities to communicate with state and local officials during a disaster (81 FR 63860, September 16, 2016). Therefore, in the event of such an emergency, we would expect that patients that are determined for safe discharge to a personal home that may have been adversely impacted should not be directed to shelters without prior consultation with public health and emergency management officials overseeing those shelters. Additionally, we would expect that patients that are anticipated to be discharged to another inpatient facility that may be adversely impacted should not be sent to a shelter without prior consultation with public health and emergency management officials overseeing those shelters and with health care coalitions, where available, that may know of other inpatient facility options. In addition, we refer readers to guidance from Office for Civil Rights on emergency preparedness and ensuring at risk individuals have access to emergency services at the following link: https://www.hhs.gov/civil-rights/for-individuals/special-topics/emergency-preparedness/index.html.

Comment: We received several comments regarding community based care organizations. Comments included the following recommendations:

- Mandate that providers collaborate and coordinate with community based organizations on the availability of community supports at discharge.

- Include specific references to CILs, ADRCs, and AAAs in the regulation and provide patient instructions on their use.
- Clarify how collaboration between hospitals and community based organizations would be encouraged and funded, including requiring Medicare and Medicaid reimbursement of AAAs and community-based organizations.
- Require that community based providers be included in the early stages of planning for a patient's discharge.
- Clarify how a hospital would know what facility or agency a patient would use before discharge.
- Clarify timelines for considering the availability of, and access to, non-health care services for patients, specifically in instances where the post-acute care provider had a physical accessibility issue.

Response: As we have already stated in this final rule, we believe that community based care organizations, including CILs, ADRCs, and AAAs, play an important part in helping individuals, who are returning home or who want to avoid institutionalization, by connecting them to community services and supports. Currently, many of these organizations already help older adults and people with disabilities with transitions across settings, from hospitals and PAC settings back to home. Because of the important role that community based organizations play, we strongly encourage hospitals to develop collaborative partnerships with providers of community-based services. We believe that such collaboration will help with successful patient transitions.

While we encourage, and even urge, collaboration with organizations such as CILs, AAAs, and ADRCs to assist patients with access to LTSS, we believe that

mandating a collaborative relationship could be overly burdensome for hospitals. In order to demonstrate compliance with a proof of collaboration requirement like the one recommended here by some commenters, hospitals would need to provide extensive documentation solely for Medicare certification and participation purposes. Such an approach runs counter to current CMS initiatives to place patients over paperwork. Hospitals should be afforded the flexibility to provide information about these organizations and collaborate with these entities as is appropriate for the patient and based on the patient's goals of care and treatment preferences. We expect that hospitals would be responsive to the patient regarding his or her needs and provide information to the patient about these organizations as well as form collaborative relationships with these entities as appropriate.

This final rule does not mandate a specific methodology for how collaboration between hospitals and community based providers should be conducted nor does it mandate that hospitals (when developing a patient discharge plan) must consider a patient's eligibility for community based services, any patient wait lists for services, or any time frames established by community based providers for the initiation of services. We believe that such detailed mandates would be overly burdensome for hospitals and inappropriate for these regulations. However, as we stated above, we are finalizing a requirement at § 482.43(a)(2) that a hospital include an evaluation of a patient's likely need for appropriate non-health care services and community based care providers, and must also include a determination of the availability of, and the patient's access to, those services as part of the patient's discharge planning evaluation. We encourage hospital personnel to be knowledgeable about the services that are provided by their local

community based organizations and expect hospital personnel to be able to offer their patients guidance on how to connect with their local community based organizations. Once a patient is discharged, we would not expect hospitals and CAHs to be responsible for ensuring that a patient has received non-health care services (including home modifications), as this would be outside the scope of a hospital's or CAH's responsibility. Once a patient is connected with a community based organization, such as an ADRC, AAA, or CIL, the responsibility for ensuring that the patient is actually receiving non-health care services, including home modifications, becomes that of the community based organization and the community provider of the services and supports. We also do not believe that hospitals and CAHs should hold patients until physical accessibility issues are resolved, although we understand that sometimes hospitals hold patients until a bed is available at a corresponding PAC facility. Hospitals and CAHs can provide patients with resources regarding supportive housing and home and physical environment modifications including assistive technologies and, where appropriate, medical equipment and supplies, including back-up batteries. We refer readers to further guidance that can be found in the previously provided web links in the discussion on the proposed requirements for § 482.43(c)(5) and on the final requirements for § 482.43(a)(2) of this final rule.

Finally, comments regarding funding for community based organizations are outside the scope of this rule.

Comment: Many commenters supported the proposal to require that the discharge plan address the patient's goals of care and treatment preferences. A few commenters asked for clarification on how hospitals will be expected to demonstrate the incorporation

of the patient's goals and wishes into the plan. The commenters gave specific examples of instances where patients may leave against medical advice, may be undocumented and not as forthcoming about information, or patients who may be embarrassed about needing social services. The commenters noted that hospitals should try to work with the patients as much as possible and should not be penalized if patients decline medical or discharge planning assistance. One commenter stated that sometimes patient goals and preferences are not consistent with the clinical needs of the patient or the resources available to the patient post-discharge. Therefore, the commenter concluded that the patient's goals and preferences cannot be fully accommodated in the final discharge plan. The commenter recommended that CMS modify the language used in the rule and clarify that the patient's goals and preferences must be considered during the discharge planning process, but that it is ultimately the decision of the practitioner responsible for the care of the patient whether the goals and preferences can be incorporated into the discharge plan.

Response: While we are modifying this proposal by finalizing it in the introductory paragraph at § 482.43, we note that we still expect that the patient's goals of care and treatment preferences would be included in the patient's medical records. Similarly, we understand that situations may arise where patients may be uncooperative or may refuse to participate in the discharge planning process. We also expect hospitals and CAHs to document the patient's refusal to participate in the discharge planning process, and that such attempts to incorporate the patient and/or the patient's caregiver in the discharge planning process were made, in the medical record. While we understand the commenter's concerns that a patient's goals of care and treatment preferences might not always align with the practitioner's recommended medical care, we continue to

believe that it is important for hospitals and CAHs to develop and implement an effective discharge planning process that focuses on and, where appropriate, is consistent with the patient's goals and preferences. We expect that these goals and preferences will be included in the discharge plan and would reasonably relate to the patient's medical care or treatment preferences, preferred non-health care services, post-acute care, or community-based care post-hospitalization. While we expect that practitioners will establish the most appropriate course of care for their patient and document this in the patient's discharge plan, we note that patients cannot be forced to follow their discharge plan and that patients have the right to refuse treatment or to leave the hospital or CAH against medical advice.

Final Decision: After consideration of the comments we received on the proposed rule, we are finalizing the discharge planning requirements with the following modifications:

- Revising the language in the introductory paragraph of § 482.43.

- Revising and redesignating proposed § 482.43(a), (b), and (c) as § 482.43(a) "Discharge planning process." As revised, § 482.43(a) will incorporate and combine provisions of the current hospital discharge planning requirements (some of which are statutorily required for hospitals) with revised elements contained within some provisions of the proposed requirements at § 482.43(c).

- Redesignating the requirements in proposed § 482.43(c)(10) as § 482.43(a)(7), which would still require hospitals to assess their discharge planning processes on a regular basis, which would 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.

- Withdrawing our proposal at § 482.43(c) to require that 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.

- Revising and redesignating the requirements in proposed § 482.43(c)(1) to state that any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel. We are finalizing these requirements as § 482.43(a)(5).

- Revising and redesignating § 482.43(c)(2) to eliminate the 24-hour time frame requirements and retaining, with minor revisions, the current requirements at § 482.43(a) to state that the hospital must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning. The hospital must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, the patient's representative, or patient's physician. We are finalizing these requirements as § 482.43(a).

- Finalizing proposed § 482.43(c)(3) without modification and redesignating these requirements as § 482.43(a)(6) to state that 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. Withdrawing proposed § 482.43(c)(4). Revising § 482.43(c)(5) to state that a discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-hospital extended care services, and home health services, and non-health care services and community based care providers, and must also determine the availability of the appropriate services as well as of the patient's access to those services. We are including these requirements as § 482.43(a)(2).

- Revising § 482.43(c)(6) to state that the discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative). This requirement will be included in § 482.43(a)(3).

- Modifying § 482.43(c)(7) by requiring that hospitals have an effective discharge planning process that focuses on the patient's goals and preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to preventable hospital readmissions. These requirements are included in the introductory paragraph at § 482.43.

- Modifying the requirements at proposed § 482.43(c)(9) to state that any discharge planning evaluation must be made on a timely basis to ensure that appropriate

arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge. We are finalizing these requirements in § 482.43(a)(1).

- We are making a technical revision to the proposal at § 482.43(c) to clarify the intent of the requirements related to *post-acute care services*. This requirement applies to patients whose discharge plan includes a referral to HHA services or transfer to a SNF, IRF, or LTCH.

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

We proposed 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, and who require: follow-up with their PCP and/or a specialist and who might also be receiving post-acute care from HHAs, hospice services, and/or any other type of outpatient health care services. The phrase "patients discharged to home" would not refer to patients who are transferred to another inpatient hospital or CAH, inpatient hospice facility, or a SNF.

Proposed § 482.43(d)(1): We proposed 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 and who also might be referred to PAC services. We also proposed that practitioners/facilities (such as an 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.

Proposed § 482.43(d)(2): We proposed to set forth the minimum requirements for discharge instructions as follows: instructions to the patient and his or her caregivers about care duties that they would need to perform in the patient's home as determined in the patient's discharge plan; written information on the warning signs and symptoms that patients and caregivers should be aware of with respect to the patient's condition; all medications prescribed and over-the-counter for use after the patient's discharge from the hospital (with reconciliation of all medications used by the patient prior to admission), including the name, indication, and dosage of each medication along with any significant risks and side effects of each drug as appropriate to the patient; written instructions, in paper or electronic format (or both), provided to the patient; and documenting 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.

Proposed § 482.43(d)(3): We proposed to require hospitals 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; and all other necessary information, as specified in proposed § 482.43(e)(2).

Proposed § 482.43(d)(4): We proposed to require, for patients discharged to home, that the hospital establish a post-discharge follow-up process.

Comment: Numerous commenters expressed overall disagreement with the overly detailed, prescriptive nature of the proposed requirements. While they supported the overall goal of improving discharge planning, commenters expressed concern about overburdening discharge planning staff, duplicating existing hospital discharge planning practices, and diverting patient care resources to regulatory process requirements.

Response: We are sensitive to the concerns expressed by commenters, as we share their goal of streamlining the regulations to balance the need for minimum health and safety requirements with the need for maximum hospital flexibility to achieve patient outcomes. In light of the concerns expressed by commenters, we have removed the majority of the proposed requirements, specifically those at § 482.43(d)(1), (2), and (4), and have significantly revised the requirements of proposed § 482.43(d)(3) to reduce regulatory burden.

Comment: Several commenters supported the proposal to provide discharge instructions to the patient and/or the patient's caregiver/support person(s), and the PAC provider or supplier, if the patient is referred to PAC services. Additionally, some commenters sought clarification regarding specific issues, such as whether hospitals could share post-hospital care instructions with the patient and/or the patient's caregiver prior to actual discharge and whether there would be HIPAA violations when a hospital sent discharge instructions to the PAC provider or supplier.

Response: Although we are not finalizing this requirement as proposed, hospitals or CAHs are not prevented from developing discharge instructions or sharing discharge information in accordance with applicable law earlier than the time of discharge. Additionally, we note that providing a patient with his or her discharge instructions is a

long-standing standard of practice for hospitals when discharging inpatients as well as when releasing patients from care in other areas of the hospital (for example, the emergency and ambulatory surgery departments). Because of this, we believe that it is unnecessary to specifically require it here, but we encourage hospitals and CAHs to continue this long-standing standard of practice that serves as a simple way of not only informing, but also engaging, the patient (and/or the patient's caregiver/support person(s)) regarding his or her continued care upon discharge from the hospital or CAH. We note hospitals, HHAs, and CAHs are required to send certain discharge information to the PAC provider or practitioner(s) responsible for follow-up care, if the practitioner is known and has been clearly identified. We have no reason to believe that sending discharge information to such PAC providers or suppliers would be considered a HIPAA violation, since disclosures for treatment, care coordination, and quality improvement purposes are generally permitted under 45 CFR part 164.

Comment: Several commenters recommended that hospitals use the National CLAS Standards for guidance on providing instructions in a culturally and linguistically appropriate manner and also recommended the use of the "teach-back" method to confirm the patient's or the patient's caregiver/support person's (or both) understanding of the discharge instructions.

Response: While we are not finalizing the proposed discharge instruction requirements discussed here (in response to public comments that noted the overly detailed, prescriptive nature of these proposed requirements) and although we also did not propose requirements that included the commenters' recommendations, we would still like to encourage hospitals to consider these recommendations for their discharge

planning processes. Therefore, we refer readers to the following links for more information regarding the use of the "teach-back" method during the discharge planning process as well as for additional information on the National CLAS standards:

- https://www.thinkculturalhealth.hhs.gov/clas/standards.
- http://www.teachbacktraining.org.

Comment: A few commenters submitted comments regarding documentation. One commenter stated that hospitals should be required to include the patient's discharge instructions in the medical record, and that the medical record should also include documentation that the patient and caregiver were offered a demonstration of post-discharge care tasks and an opportunity to ask questions and receive answers on post-discharge care. A few commenters asked for clarification on the documentation requirements for patients that leave against medical advice.

Response: We encourage hospitals and CAHs to document interactions with patients and/or their caregivers in the medical record as a best practice. Patient discharge instructions, as part of the record of patient care in the hospital, are already required to be included in the medical record under the Medical Record Services requirements in § 482.24, so no new requirement is needed here. We understand that situations may arise where patients may prefer not to participate in the discharge planning process. For patients that decline to participate in the discharge planning process or leave the hospital or CAH against medical advice, we expect hospitals to document in the medical record the patient's refusal to participate in the discharge planning process, and that such attempts to include the patient and/or the patient's caregiver in the discharge planning process were made by hospital staff.

Comment: We received several comments related to the content and implementation of the proposed discharge instructions requirement. While some commenters suggested that CMS include even more specificity in the requirements, most expressed concern that CMS was requiring too much information be provided to the patient upon discharge, and that CMS should not mandate what should be included in the discharge instructions. One commenter also disagreed with the requirement that discharge instructions be written, and requested that CMS allow for other communication methods to share this information with patients.

Response: We believe that the requirements of this section, as proposed, are overly prescriptive and we do not believe that it is appropriate to finalize a requirement that hospitals must provide specific written discharge instructions to patients. We believe that the overall involvement of the patient and caregivers, as set forth in §§ 482.43 and 485.642, in addition to the already established practice of providing discharge instructions appropriate to each patient as is the current standard of care, will ensure appropriate communication between providers, patients, and caregivers throughout the discharge planning process.

Comment: A few commenters asked about the role that Prescription Drug Monitoring Programs (PDMPs) should play in the discharge planning process.

Response: As part of the medication reconciliation process, in the proposed rule we encouraged practitioners to consult with their state's PDMPs. We also solicited 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 as indicated by the PDMP report. While we continue to believe that practitioners should consult with

their state's PDMP if they believe it appropriate to do so, we are not mandating the use of PDMPs at this time. We further note that our rule does not preempt or conflict with state laws that may require hospital consultation with PDMPs or other PDMP-related actions. We also refer readers to the discussion on PDMPs in section II.C of this final rule.

Comment: Most commenters supported the proposed requirement that hospitals send a copy of the discharge instructions and the discharge summary, pending test results, and other necessary information to the practitioner(s) responsible for follow-up care, if the practitioner is known and has been clearly identified, and cited the importance of this information for these practitioners. However, most commenters stated that the required timeframes were overly prescriptive and requested more flexibility pertaining to these timeframes. Several commenters noted the challenges that the lack of adoption of interoperable health IT among follow-up practitioners poses for hospitals. Two commenters requested that, instead of sending test results, hospitals instead be required to make such test results available or accessible to the follow-up practitioner(s). Two commenters felt that the timeframes included in the proposed rule were too flexible and that the required information should be sent to the practitioner(s) responsible for the follow-up care of the patient at the time of discharge to prevent any unnecessary delays in the patient's follow-up treatment.

Response: We agree with the commenters that specific timeframe requirements may not be reasonable or appropriate in all situations. In this final rule, we are eliminating the specific timeframe requirements proposed in this section and revising the requirements for hospitals and CAHs to send information to the practitioner(s) responsible for follow-up care prior to the patient's first follow-up visit with the

practitioner(s). We further note that we are finalizing a requirement that hospitals and CAHs must discharge the patient, and transfer or refer the patient where applicable, *along with all necessary medical information* pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the practitioners responsible for the patient's follow-up or ancillary care at § 482.43 (b). We refer readers to section II.E.7 of this final rule for a more detailed discussion of this requirement.

We are not proposing a specific form, format, or methodology for the communication of this information; however, 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 note that HHS has a number of initiatives designed to encourage and support the adoption of health IT and to promote nationwide health information exchange to improve the quality of health care. While pending test results clearly would be included as part of a patient's necessary medical information that we are requiring be sent upon discharge to facilities and practitioners providing PAC and follow-up services to the patient, we also recognize that the very nature of these test results being "pending" precludes them from being sent at that time and hospitals would not be held accountable for sending information that they simply do not have at the time of discharge. We encourage hospitals and CAHs to find their own innovative and unique solutions to solve this issue, including any means that would ensure that these pending results are available and accessible to the appropriate facilities and practitioners at the appropriate time.

Comment: Many comments were submitted regarding the requirement to provide discharge information to the practitioner(s) responsible for follow up care. One commenter stated that the list of information may be duplicative and, in some cases, excessive. The commenters added that for patients following up with their primary care provider, many of the preventive and baseline medical history items, as well as a psychosocial assessment, would already be known to the provider. Two commenters recommended that CMS require hospitals to provide the required necessary medical information, to dialysis facilities, dialysis units, or nephrologists within 48 hours of discharge. A few commenters questioned how the hospital would monitor the information sent by the hospital to the practitioner(s) responsible for follow -up care of the patient who is being discharged to their home.

Response: We have revised this requirement to remove a number of items that were proposed to be included as part of what many commenters described as an overly and unnecessarily prescriptive list of patient medical information that was to be sent. In this final rule, the hospital is now only required to provide certain necessary medical information that we believe allows a hospital the flexibility to effectively determine and align the pertinent patient information with a specific patient based on the clinical judgment of the practitioners responsible for the care of the patient since they are the practitioners who know the patient best while he or she is receiving care in the hospital. As many commenters noted, and with which we agree, a more flexible regulatory approach, such as we are finalizing here, allowing for the determination and transfer of a particular patient's necessary medical information will provide a more thoughtful and effective means to ensure better continuity of care for a patient being discharged.

However this requirement as finalized in this rule will not limit the types and amount of patient information that can be shared with practitioners responsible for the patient's follow-up or ancillary care, but will also allow the inclusion of any additional clinically relevant information that the hospital's or CAH's practitioners believe would be beneficial for the patient's transition from one care setting to another.

Similarly, this requirement that a patient's necessary medical information must be transferred at the time of discharge (and transfer or referral as applicable) to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care would also include dialysis facilities, dialysis units, and nephrologists for those patients where this is relevant and appropriate. Therefore, we respectfully disagree that mandating specific provider and supplier types as well as specific categories of practitioners in these requirements is necessary or appropriate. We note that we encourage providers to include any additional necessary medical information as part of the discharge summary as appropriate and also encourage them to ensure that any specific providers or suppliers or specialty practitioners that are clinically relevant to a particular patient be included in the conveyance of the necessary medical information upon discharge; for instance, when the hospital's health IT system is used to populate a discharge summary with relevant information from the patient's record. The hospital will not be responsible for monitoring information if it has been provided to the practitioner.

Further, we understand that there are special care needs for patients that are diagnosed with chronic illnesses such as kidney disease, diabetes, etc., and our requirements allow facilities to address and acknowledge these needs by sending a

patient's necessary medical information to a special needs facility/provider such as a dialysis facility or nephrologist, if this information is known. However, we believe it would be burdensome to specifically mandate that facilities send this information to these providers and practitioners, or to prescribe a specific timeframe for sending the information. Instead, we are allowing facilities to have the flexibility to determine when and if this information should be sent. However, we must note here again that a patient's dialysis care plan information is part of his or her necessary medical information. We believe that this information should be conveyed upon discharge or transfer since such information is clearly necessary medical information and should be transferred with the patient. As for all requirements in this regulation, further implementation guidance will be provided. Furthermore, we believe that providing pertinent information such as specialized assessments and information regarding DME needs is a valuable piece of necessary medical information. We also expect that hospitals are providing any necessary requested information to follow up providers.

Comment: One commenter stated that the discharge instructions should be provided to HHAs prior to or at the time of discharge when the patient is referred to home health services following discharge to home from the hospital. The commenter also suggested that in cases in which the patient was receiving home health services prior to the current hospitalization, hospitals should be required to maintain ongoing communications with the HHA. The commenter believes that the HHA that was providing services to the patient prior to the current hospital admission should continue to be the patient's PAC provider should the patient be referred for home health services following the current inpatient admission if the patient chooses.

Response: While we have revised and relocated some of the proposed requirements in this final rule, we have essentially retained (with some clarifying modifications as well as the addition of some important elements of the proposed requirements for this section) the current requirement that the hospital must transfer or refer the patient, along with his or her necessary medical information, to appropriate facilities, agencies, or outpatient services, as needed, for follow-up or ancillary care upon discharge. We are finalizing the requirement as standard (b) "Discharge of the patient and provision and transmission of the patient's necessary medical information," will require the hospital (or the CAH) to discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

In this final rule, the patient must be referred to a Medicare-participating HHA that serves the geographic area (as defined by the HHA) in which the patient resides. It is expected that the patient be referred to an HHA that can meet the clinical needs of the patient as indicated in the patient's discharge plan. If the patient was receiving home health services prior to the current hospital admission and the patient is referred for home health services following their discharge from the current admission, we expect that the patient be given the option to continue to receive services from the same HHA if they so choose so long as the HHA is still appropriate to meet the needs of the patient and the HHA still meets the requirements under proposed § 482.43(f)(1) (finalized here as

§ 482.43(c)(1)). We do not believe that we should require a patient to maintain a relationship with a provider if the patient wishes otherwise.

Comment: One commenter suggested that we develop a policy that would facilitate improved payer-provider collaboration and coordination with the discharge planning process so that managed care companies are also held to these same requirements.

Response: This comment pertains to the oversight of managed care organizations rather than to any specific proposed changes to the discharge planning policy proposals set forth in the Discharge Planning proposed rule. The comment is therefore outside the scope of this final rule.

Comment: One commenter questioned if there should be a requirement for the hospital to use reasonable efforts to determine the identity of the practitioner(s) responsible for the follow-up care of the patient being discharged to home, and to communicate with that practitioner.

Response: We expect that hospitals are already using reasonable efforts to determine who the practitioner(s) responsible for the follow-up care of the patient is and, in many cases, hospitals are scheduling the follow-up appointments for those patients who are being discharged to home. Most hospitals have discharge policies in place that include assigning patients to one of their physicians who see outpatients – either on staff or who have privileges at that hospital, if the patient does not have a primary care physician or an appropriate practitioner who is responsible for the follow-up care of the patient. Thus, we expect hospitals will have processes in place to routinely and consistently identify a follow up practitioner for every patient discharged.

Comment: While commenters supported the goals of a post-discharge follow-up process, some commenters noted that the evidence is still being developed on how best to do this and disagreed that all patients would even require post-discharge follow-up.

Response: While we continue to believe that a post-discharge follow-up process has value for certain patients, for the reasons we gave in the proposed rule (80 FR 68135), we have decided to remove this requirement from this final rule since we believe that most hospitals are already doing this according to their specific situations and patient populations, and patient risk levels. We note the importance of ensuring that hospitals follow-up, post-discharge, with their most vulnerable patients, including those with behavioral health conditions. As a result, we encourage hospitals to research evidenced-based best practices and determine and implement a process that best meets the needs of their patient population. It should be noted that CMS continues to use other levers at its disposal, which are separate from the regulatory ones in the CoPs discussed here, to encourage reductions in the number of unnecessary readmissions and to improve post-discharge patient outcomes. This emphasis on reducing preventable readmissions, especially for the most vulnerable patient populations, remains a high priority for CMS.

Comment: Several commenters requested that we investigate payment models that will support the hospital's establishment of a post-discharge follow-up process for patients discharged to home. One commenter stated that health plans should be responsible for following up with their enrollees after a hospital discharge.

Response: These comments do not pertain to any specific proposed changes to the discharge planning policy proposals, and therefore are outside the scope of this final rule.

Final Decision: After consideration of the public comments we received on the proposed rule, we are not finalizing § 482.43(d). We are redesignating the proposed requirement in § 482.43(d)(3) as § 482.43(b), and we are eliminating the specific timeframe requirements to require that hospitals discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the practitioners responsible for the patient's follow-up or ancillary care.

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

We proposed to re-designate and revise the current standard 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. Therefore, we proposed, 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 directives, 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, we proposed that 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. We also proposed to require hospitals provide this information at the time of the patient's discharge and transfer to the receiving facility.

Comment: We received numerous comments regarding the requirement for hospitals and CAHs to provide specific information to a receiving facility during a transfer. While some commenters supported the proposed list of elements and offered suggestions for additional elements, most commenters believed that the list of required necessary medical information was overly prescriptive, excessively extensive, time consuming, duplicative, and burdensome. Some commenters stated that the extensive list would not improve the transition of patient care. Commenters suggested that the list be pared down or eliminated in favor of a clinical summary of a patient's hospitalization. Commenters recommended that specific information be determined by hospitals or CAHs and that only essential information be sent with the patient in the case of a transfer. One commenter recommended that CMS provide additional information on what constitutes sufficient information regarding certain medical information elements specified in the proposed rule including: functional status, advance care plans, transportation needs, and risk assessment. Another commenter recommended that information regarding a patient's behavioral health issues include federally required preadmission screening for persons with serious mental illnesses or mental disabilities, as required for Medicaid Nursing home patients in section 1919(e)(7) of the Act.

Several commenters expressed concern that the proposed requirements aligned with the Common Clinical Data Set defined in the 2015 Edition final rule and questioned the appropriateness of this alignment at this time, while other commenters supported the alignment. A few commenters had specific concerns about the inclusion of unique device

identifier(s) for a patient's implantable device on the list of necessary medical information. While the commenters note their support of the use of the unique device identifier, they note that the required use at this moment is premature.

Response: We continue to strive to promote successful transitions of care between health care settings and 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. Doing so will improve patient safety and potentially reduce hospital readmissions. Most providers recognize the importance of improving transitions of care between health care settings and several states and organizations have begun to develop, use, and recommend continuity of care documents or universal transfer forms. 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 (http://innovation.cms.gov/initiatives/CCTP/index.html) and AHRQ as well as through a number of professional organizations, including the National Transitions of Care Coalition (www.ntocc.org). We refer readers specifically to the following information provided by AHRQ regarding care transitions:

- https://www.ahrq.gov/professionals/systems/hospital/engagingfamilies/strategy4/index.html
- https://innovations.ahrq.gov/qualitytools/care-transitions-program-toolkit
- https://caretransitions.org/tools-and-resources/
- https://www.ahrq.gov/professionals/systems/hospital/red/toolkit/index.html

Therefore, we continue to believe that hospitals and CAHs should be required to send certain necessary medical information to a receiving facility upon a patient's

transfer. However, we agree with commenters that mandating the various data elements listed in the proposed requirement may be burdensome to providers and may have the unintended effect of hindering a patient's discharge. However, while we are not requiring an extensive list of items as originally proposed, we still expect facilities to send certain necessary medical information that is critical to the care of the patient and pertinent to the patient's specific medical status at the time of discharge. We also believe facilities should have discretion to send the most relevant information within the required necessary medical information, consistent with "clinical relevance" as defined in the Medicare and Medicaid Electronic Health Record Incentive Program final rule (80 FR 62761, October 16, 2015) ("2015 Meaningful Use Rule"). Other important and pertinent information that should be conveyed at discharge or transfer would be current diagnoses (including any behavioral health issues of mental health and substance abuse), laboratory results (including *Clostridium difficile* and multi-drug resistant organism status, as well as any antibiotic susceptibility testing, as applicable), and patient functional status, to name just a few broad areas of medical information that we believe are critical to patient care.

Therefore, we are revising and relocating our proposed requirement from § 482.43(e) to § 482.43(b) in this final rule to require that a hospital must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

This modification aligns with our goals to promulgate CoPs that contain baseline requirements for providers that protect the patient's health and safety while allowing for provider flexibility and reducing unnecessary provider burden. While we continue to believe that much of the information we proposed should be exchanged for patients to whom it applies, as well as many of the additional suggestions we received, we are requiring a less prescriptive and more flexible set of requirements. We understand that the information required may vary based on the circumstances of a patient's discharge to home or transfer to another health care facility, including the urgency of the transfer.

We note that providers can and should send all additional medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences. In addition, we expect that certain information, including a patient's goals and treatment preferences, be included in the patient's discharge or transfer summary and any other relevant documentation.

We plan to issue sub-regulatory guidance that will discuss the circumstances of when a discharge or transfer summary would be expected at the time of discharge (and transfer if applicable), as in a discharge to home and community-based services (or a transfer to a PAC services facility such as a SNF), versus when it would not be appropriate to delay an emergency transfer as a result of waiting on the availability of a discharge summary. From our experiences with hospital and CAHs, we are also aware that there are instances when the discharge or transfer summary is delayed in being sent by the hospital or CAH due to the lack of a signature at the time of discharge by the practitioner responsible for the care of the patient. We note here that neither the current CoPs nor the revisions finalized in this rule prohibit hospitals and CAHs from sending an

interim discharge or transfer summary document that would include the required necessary medical information to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care so that such information can be shared timely, so that the discharge and/or transfer is not further delayed, and so that those facilities and practitioners responsible for the patient's follow-up or ancillary care are provided sufficient and necessary information and time to prepare to receive the patient. We would expect that a finalized document, even if not significantly different from the interim one, would follow the patient. Such practices are not only allowed under the CoPs, but also can be seen as constituting "best practices" for ensuring effective continuity of care for the patient transitioning from one care setting to another.

Additionally, we would also like to point out that in those hospitals and CAHs where there are multiple licensed and qualified practitioners responsible for the care of the same patient, delay of the discharge, and transfer or referral where applicable, of the patient, along with his or her necessary medical information, should not occur as a result of "waiting" for a specific provider's signature, either written or electronic, on the discharge order and the discharge or transfer summary for the patient. The CoPs allow for orders and other forms of patient medical record information (for example, H&Ps, progress notes, discharge/transfer summaries, etc.) to be documented and signed by a licensed and qualified practitioner who is responsible for the patient as long as the practitioner is acting in accordance with all state and local laws, including scope-of-practice laws, as well as with all hospital and medical staff requirements and bylaws, and with any individual privileges granted to the practitioner by the governing body.

While we have increased the flexibility in these requirements, we continue to support the alignment discussed in the proposed rule between this approach and the Common Clinical Data Set, which health care providers are electronically exchanging through the use of certified EHR technology (80 FR 62693). We encourage facilities to identify opportunities to streamline data collection and exchange by using data they are already capturing electronically. While we are finalizing a broad requirement for sending necessary medical information, rather than listing data elements, such as those explicitly aligned with the data referenced as part of the Common Clinical Data Set (CCDS) that was finalized in the 2015 Edition final rule (80 FR 62858), eligible hospitals and CAHs in the Promoting Interoperability Program are required under 42 CFR 495.4 to use EHR technology certified to the 2015 Edition health IT certification criteria beginning in CY 2019 and are therefore required to provide the elements in the CCDS as part of a summary of care record (81 FR 77555). We note that by finalizing the requirement to release certain medical information in this final rule in accordance with all applicable laws, we are ensuring that the CoPs do not conflict with the CCDS. The CoPs do not bar providers from sending all additional appropriate medical information regarding the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences in accordance with applicable laws. We expect that certain information, including a patient's goals and treatment preferences, would be included in the patient's discharge summary and any other relevant documentation. As we note above, we plan to issue further sub-regulatory guidance that will discuss the circumstances of when a discharge summary or transfer summary would be expected at the time of discharge (and transfer if applicable). Furthermore, the interpretive guidelines

for requirements in this final rule will be released sometime following the publication of this final rule, which will provide additional information regarding alignment with the CCDS, where applicable.

Providers must continue to comply with all pertinent laws, including the HIPAA Privacy Rule and the behavioral health privacy regulations referenced by the commenter, as they implement these discharge planning requirements. Finally, we generally consider the exchange of information between facilities using an EHR system the same as "sending" information from one facility to another, except under those circumstances when we explicitly require use of a physical record. In fact, we expect that facilities, which are already electronically capturing patient health care information, are also electronically sharing that information with providers that have the capacity to receive it to the extent such release is permitted under HIPAA.

Comment: One commenter recommended that CMS encourage, but not require, hospitals to send the discharge or transfer summary to PACs as far in advance as possible, while another commenter recommended that CMS make this a requirement. In addition, the commenter recommended that CMS mandate that the referring facility ensure that the receiving facility has received the information.

Response: We agree that there are benefits to sending necessary medical information to post-acute care services providers as far in advance as possible and encourage hospitals to do so. However, we do not agree that this should be a requirement for all hospitals and CAHs. We also note that we are not requiring hospitals and CAHs to ensure that the receiving facility has received the information on a patient's discharge because such a requirement would be overly burdensome.

Comment: A few commenters recommended that CMS delineate specific methods of communicating necessary medical information between the hospital and the PAC provider at the time of discharge. The commenters noted that designating a specific method will allow for seamless transmittal of data between settings

Response: We are not requiring that hospitals and CAHs transmit necessary medical information in a specific manner at this time. However, we believe that it is absolutely important for PAC providers to receive information from hospitals and CAHs regarding a patient's vital and pertinent information, and we encourage hospitals and CAHs to send the information prior to discharge if at all possible and make the necessary revisions to allow for this as described previously. Furthermore, we encourage hospitals and CAHs to send this necessary medical information electronically, if the PAC provider has the capacity to receive it in this manner.

Comment: One commenter requested that CMS create an exception for real time discharge summaries for transfers from acute care to SNF facilities. The commenter noted that while it is essential to know a patient's medical and treatment history, the discharge summary requirement does not make sense if information is being sent when the transfer is from the "doctor to him or herself" and from the "nurse to the same nurse." The commenter further pointed out that this may be an issue in rural communities, where the practitioners are the same on either side of the transfer.

Response: We understand the commenter's concerns about a repetitive or time consuming process for rural or small hospitals or CAHs, particularly when the services being provided to the patient changes from acute inpatient to swing bed. We note that the

discharge planning process does apply to patients whose status changes from acute inpatient to swing bed services.

Final Decision: After consideration of the comments we received on the proposed rule, we are finalizing § 482.43(e) with modifications. We are revising and redesignating § 482.43(e)(2) as follows:

- Removing proposed § 482.43(c), (d), and (e) and replacing these standards with revised and redesignated § 482.43(b), entitled "Discharge and transfer of the patient and provision and transmission of the patient's necessary medical information." The final standard at § 482.43(b) incorporates and combines revised provisions from the proposed requirements at § 482.43(c), (d), and (e).

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

We proposed to re-designate and revise the requirements of current § 482.43(c)(6) through (8) at new § 482.43(f), Requirements for PAC services. The proposed standard is based in part on specific statutory requirements located at sections 1861(ee)(2)(H) and 1861(ee)(3) of the Act. We proposed to further clarify that the PAC providers mentioned in the IMPACT Act, specifically LTCHs and IRFs (rehabilitation hospitals and rehabilitation units of hospitals and CAHs), would also be subject to the proposed revision to the hospital CoPs in order to provide consistency with the IMPACT Act. We proposed that for patients who are enrolled in Managed Care Organizations (MCOs), the hospital must make the patient aware that the patient or caregiver needs 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 and 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.

Comment: One commenter suggested that we require hospitals to communicate the capabilities and limitations of PAC facilities to the patient to ensure the patient receives the appropriate level of care as indicated in their discharge plan. The commenter further suggested that certain additional elements be considered, including limitations of the facility's number of RNs, Certified Rehabilitation Registered Nurse (CRRNs), physician availability, amount of therapy, and access to emergency services.

Response: We understand that the commenter is concerned about meaningful and successful transitions of care between the hospital and PAC settings. However, we do not believe it is appropriate to add language requiring hospitals to communicate the capabilities and limitation of PAC facilities to the patient and/or their caregivers, as this would be duplicative of the requirement at proposed § 482.43(c)(8), now finalized at § 482.43(a)(8). We believe this requirement for sharing and using PAC data with patients sufficiently addresses the commenter's concerns.

Comment: Several commenters requested that we design a process or tool to allow for rapid identification of appropriate PAC organizations, including those that are in the patient's managed care network, to speed up the discharge process. One commenter recommended that CMS require insurance companies to have an updated list

of providers and rating qualities and cost efficiency data so that providers can refer patients to their insurance companies for this information. One commenter stated that obtaining a list of Medicare-certified providers was challenging and that information regarding the providers was not always up to date.

Response: We would allow a hospital the flexibility to implement the requirement to present its list of HHAs, SNFs, IRFs, or LTCHs in a manner that is most efficient and least burdensome in its particular setting. For HHA, SNF, and dialysis services, a hospital can access a list from the CMS Web site, at http://www.medicare.gov, or develop and maintain its own list of HHAs and SNFs. We expect that providers have the most current list of providers that is available to them at the time. When the patient requires home health services, the CMS Web site list can be accessed based on the geographic area in which the patient resides. When the patient requires post hospital extended care services, the CMS Web site list would be accessed based on the geographic area requested by the patient. Or, in the rare instance when a hospital does not have Internet access, the hospital can call 1–800–MEDICARE (1–800–633–4227) to request a printout of a list of HHAs or SNFs in the desired geographic area. Information on this Web site should not be construed as an endorsement or advertisement for any particular HHA or SNF. For IRFs and LTCHs, we expect that hospitals maintain a list of their own, based on geographic location of the facilities. If a hospital chooses to develop its own list of HHAs, SNFs, IRFs, and LTCHs, the hospital would have the flexibility of designing the format of the list. However, the list should be utilized neither as a recommendation nor endorsement by the hospital of the quality of care of any particular HHA, SNF, IRF, or LTCH. If an HHA, SNF, IRF, or LTCH does not meet all of the criteria for inclusion

on the list (Medicare-certified and is located in the geographic area in which the patient resides or in the geographic area requested by the patient), we do not require the hospital to place the entity on the list. We expect that hospitals share their data sources with the patients or the patient's representatives and explain the meaning of the data as they are presented to them.

Except as specified by statute, CMS lacks the authority to require insurers, health plans, or plan sponsors to meet CMS's regulatory requirements. Because the discharge planning requirements have no provisions regarding health plans, health insurers, or plan sponsors, comments related to potential requirements for insurers are outside the scope of this final rule.

Comment: Numerous commenters made suggestions regarding the list of PAC providers that must be provided to patients. One commenter stated that we should require that the list of PAC providers given to patients include all available PAC providers, as a means to eliminate potential bias in favor of PAC providers who may have a close relationship with the hospital. Several commenters expressed concern with the requirement that HHAs must request to be listed by the hospitals as available, as this is seen as limiting the options presented to patients. One commenter stated that it is common practice for hospitals to first require PAC providers to indicate they will accept a particular patient in order to be included in the list of PAC providers that is presented to the patient. The commenter states that hospitals frequently present to the patient only the PAC providers that responded favorably within a given timeframe that they will accept the patient, even if only a limited number of providers responded to the request. Commenters recommended that the regulation be modified to include hospice among the

post-hospital care providers where a list of hospices is made available to the patient, along with the other protections on the patient's freedom of choice. Another commenter stated that hospitals should be required to provide lists of all providers and services available to patients upon discharge.

Response: We proposed at § 482.43(f)(1) to require hospitals 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. This allows the patient to identify the geographic area in which they would like the SNF, IRF, or LTCH to be located. Given that this process is patient-driven, it eliminates the risk of hospital bias in the patient's selection of one of these PAC providers. In addition, providing patients with a list of providers that responded within an allotted period of time would not assist the patient in making a decision, as it may unduly limit patient choice based on an arbitrary time deadline. While hospitals may have working relationships with some PAC providers, hospitals are expected to present patients with a list of providers that meet the proposed requirements of § 482.43(f)(1). We expect discharge planning to facilitate patient choice in any post hospital extended care services, even though the statute does not require a specific list beyond HHAs, SNFs, IRFs, and LTCHs. The proposed requirement at § 482.43(f)(2) is also important because it requires the hospital, as part of the discharge planning process, to 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. We do encourage hospitals to provide any information regarding PAC providers that provide services that meet the needs of the patient. Hospitals must not develop preferred lists of providers. If the hospital has information regarding a PAC provider's specialized services, we encourage that this information be provided to the patient as well as any culturally specific needs that the PAC providers are able to address (for example, the patient's foreign language needs, and their cultural dietary needs or restrictions).

Section 4321(a) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), codified as 1861(ee)(2)(D) of the Act, provided that the hospital discharge planning evaluation include an evaluation of the patient's likely need for post-hospital services and the availability of those services, ''including the availability of home health services through individuals and entities that participate in the program under this title and that serve the area in which the patient resides and that request to be listed by the hospital as available.'' We have interpreted this provision to require that hospitals need only indicate the availability of home health services provided by HHAs that request to be listed in the discharge plan, as opposed to the universe of individuals and entities that participate in the program. We believe that our interpretation is consistent with the BBA provision. We believe that the request to be listed protects HHAs from the possibility that a hospital or other acute care provider would misstate the HHAs service area.

Lastly, the provisions of the IMPACT Act apply to certain PAC providers only, including HHAs, SNFs, IRFs, and LTCHs. Although we proposed to modify this

currently existing requirement to include IRFs and LTCHs, in order to be consistent with the provisions of the IMPACT Act, we expect the discharge planner to facilitate patient choice in any post hospital extended care services as part of the discharge planning process.

Comment: One commenter stated that it would be helpful if patients and their caregivers were provided information regarding the out-of-pocket costs for the different PAC providers.

Response: This comment does not pertain to any specific proposed changes to the discharge planning policy proposals set forth in the Discharge Planning proposed rule. Calculating out-of-pocket costs for beneficiaries is outside the scope of this rulemaking.

Comment: One commenter stated that hospitals should be required to document the actual list of post-acute care referrals presented to the patient as a means for surveyors to determine the adequacy of the post-discharge options presented to the patient.

Response: We agree with the need to ensure that surveyors appropriately determine that hospitals are providing patients referred to HHAs, SNFs, IRFs, or LTCHs a list of providers that contains appropriate and sufficient options in accordance with this requirement. We think it is important to allow hospitals the flexibility to determine the manner in which they document in the patient's medical record that the list of PAC providers was presented to the patient or to the patient's representative. We expect that surveyors will ask to see this documentation as part of the survey process.

Comment: Most commenters agreed with the proposal to require that hospitals provide patients with information on which practitioners, providers or certified supplies are in the network of the patient's managed care organization if the hospital has this

information. Several commenters stated that information regarding providers and suppliers within a patient's managed care network was not readily available. Commenters also stated that confirming a patient's managed care network is the responsibility of the patient and to some extent the responsibility of the patient's health plan. Commenters found that it is reasonable for hospitals to use limited resources to assist certain patient populations with obtaining the patient's managed care network information and connecting with their managed care network such as those who naturally have difficulty navigating the healthcare system (such as those with behavioral health conditions or limited English proficiency). In addition, commenters stated that requiring hospitals to obtain and share this information is labor-intensive and recommend that we require PAC providers to disclose their managed care network to the hospital upon being contacted for patient referrals.

Response: We proposed that hospitals be required to make the patient aware that the patient or caregiver needs 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; however, the hospital is not expected to have the latest information, as only the MCO would have this information. While we understand that in some cases, information regarding a patient's managed care network is not available to the hospital, we encourage the hospital to make a reasonable effort to obtain this information regarding a particular post-acute care provider, especially if requested by the patient or for vulnerable patient populations as identified by the hospital in the hospital's discharge planning policy. It should also be noted that we encourage hospitals to work collaboratively with insurance

companies to ensure that the hospital has up-to-date information; this requirement is not intended to be an unreasonable burden on hospitals, but merely another factor in helping patients select the right post acute facility for them. While obtaining this information may be burdensome to the hospital in cases when it is not readily available, doing so is in the best interest of the patient so that the patient is able to obtain the referred post-acute care services. If the patient wishes to receive services from an in-network PAC provider, but there are none available in the patient's geographic area or the area requested by the patient, we encourage the hospital to assist the patient or the patient's representative in identifying in-network PAC providers that are able to provide services to the patient. We expect the hospital to address in its discharge planning policy cases in which there are no PAC providers within a patient's managed care network, to the extent that this information is known.

The hospital is required to provide patients with a list of PAC providers that serve the geographic area in which the patient resides, or in the case of SNFs, IRFs, and LTCHs, in the geographic area requested by the patient, and to inform the patient which providers are in the patient's managed care network to the extent that the hospital has this information, as previously described. In this way, patients will be provided with a complete list of PAC providers and the information available on which of these providers are in their managed care network. The hospital has the flexibility to determine the manner in which it meets the requirement to inform the patient. It should be noted that there may be cases in which the patient selects a post-acute care provider that is not in their managed care network (for example, if the patient is paying out of pocket for the post-acute care services). Requiring PAC providers to disclose their managed care

network to the hospital upon being contacted for patient referrals is outside of the scope of this rulemaking; however, we do encourage hospitals to work with the PAC providers in their geographic area to develop a system that will allow hospitals to efficiently identify whether a listed post-acute care provider is part of the patient's managed care network.

In addition, there may be cases in which post-acute care services are not recommended, but the patient wishes to obtain these services and cover the costs out of pocket. In these cases, we expect that the hospital will provide a list of PAC providers that are available to provide the services requested by the patient.

Additional information regarding enforcement of this requirement will be provided in the interpretive guidelines.

Comment: One commenter stated that providing a list of PAC providers to parents or patient representatives of pediatric patients is inappropriate for use in identifying care for the pediatric population. The commenter stated that there are a limited number of PAC providers that treat this population.

Response: We would not expect hospitals to provide patients or their representative with a list of PAC providers that do not provide services that will meet the needs of the patients. For example, we would not expect that a pediatric patient who is being discharged from the hospital and referred for home health services would be presented a list of HHAs that do not provide services to pediatric patients.

Comment: Several commenters requested that we implement further requirements that specifically address delays in the discharge process for patients being referred for post-acute care services related to authorization for services, timely

acceptance of patients by the PAC provider, and current payer contracts. Commenters stated that there are sometimes significant delays in the discharge process for patients referred for post-acute care services as a result of timely process for authorization for services for which preauthorization is often required. Commenters also stated that hospitals have little control over the time it takes for PAC providers to accept patients once they have been notified of the need for services. One commenter submitted a question regarding a scenario where a patient is ready for discharge and a bed is available at a Medicare sub-acute rehabilitation facility in the geographic area of the patient's choice. The commenters also asked if the patient chooses a higher rated sub-acute rehab facility that does not have a bed available, can the hospital issue a Hospital-Issued Notice of Noncoverage (HINN-12) to the patient.

Response: One of the goals of this rule is to prevent any undue delays in the patient discharge process. We understand that delays in the discharge process will still occur for patients for factors that are beyond the hospital's control. In such cases, any delays in the discharge process will not be attributed to the hospital.

The comments regarding the management and oversight of managed care networks and the current payer contracts and those regarding notices of noncoverage do not pertain to any specific proposed changes to the discharge planning policy proposals set forth in the Discharge Planning proposed rule. These matters are outside the scope of this rulemaking.

Comment: Commenters supported the proposal to require the discharge plan to identify any HHA or SNF to which the patient is referred in which the hospital has disclosable financial interest. Commenters requested that we discuss what level of

disclosure must be provided and offer some standard language for providers' use. One commenter asserted that a beneficiary may give priority during the discharge planning process to a provider or supplier related financially to the hospital if he or she had a good experience with the discharging hospital. The commenter recognized that, unless an exception applies and its requirements are satisfied, section 1877 of the Act (the physician self-referral law) prohibits referrals of designated health services by physicians who have financial relationships with entities that furnish such services. Because many post-acute providers and suppliers furnish designated health services (which include home health services, physical therapy services, occupational therapy services, and speech language pathology services, among others), the commenter recommended CMS consider providing guidance to hospitals regarding how to conduct discharge planning activities required under the CoPs in compliance with the physician self-referral law. As an example, the commenter noted the need for hospital discharge planning staff to be aware of both the hospital's financial interest in an HHA to which a patient is being referred, as well as whether the ordering physician has a financial relationship with the home health agency that implicates the physician self-referral law.

Response: We appreciate the support for the proposed regulations. If a hospital referred patients about to be discharged and in need of post-hospital services only to entities it owned or controlled, the hospital should disclose this information so the patient has all of the information needed to choose the facility he or she would like to visit for services. The proposed disclosable financial interest requirement is an effort to increase the beneficiary's awareness of the actual or potential financial incentives for a hospital as a result of the referral. To allow hospitals the flexibility of determining how these

financial interests are disclosed to the patient, we did not propose to require a specific form or manner in which the hospital must disclose financial interest. The hospital could simply highlight or otherwise identify those entities in which a financial interest exists directly on the HHA and SNF lists or the hospital could choose to maintain a separate list of those entities in which a financial interest exists.

We provide guidance regarding the physician self-referral law on the CMS Web Site at https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/PhysicianSelfReferral/. Outside of the advisory opinion process described at §§ 411.370 through 411.389, we are unable to provide specific guidance regarding the compliance with the physician self-referral law of any particular hospital, post-acute provider or supplier, or referring physician.

Final Decision: After consideration of the comments we received on the Discharge Planning proposed rule, we are finalizing proposed § 482.43(f) at § 482.43(c) without modification.

F. Home Health Agency Discharge Planning (Proposed § 484.58)

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 beneficiaries 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.

The current regulations at § 484.110 require HHAs to provide a copy of the discharge summary to the follow-up care provider. We proposed to update the discharge summary requirements by requiring that HHAs better prepare patients and their caregiver(s) 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. In § 484.58, we proposed to require that HHAs develop and implement an effective discharge planning process that focuses on the following:

- preparation of patients and caregivers 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 the Discharge Planning proposed rule (80 FR 68137), we also addressed the content and timing requirements for the discharge or transfer summary for HHAs. These proposed changes incorporated the requirements of the IMPACT Act. In addition, we solicited comments on the timeline for HHA implementation of the proposed discharge planning requirements. We discuss the comments we received in response to this solicitation of comments in section II.B of this final rule.

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

We proposed 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 proposed 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 would be updated, as needed, to reflect these changes.

Proposed § 484.58(a)(1) through (7)

We proposed at § 484.58(a)(1) to require that the discharge planning process include re-evaluation of patients to identify changes that require modification of the discharge plan, in accordance with the timeframes for updating the patient assessment as set forth at § 484.55. We proposed that the discharge plan would be updated, as needed, to reflect these changes. We proposed at § 484.58(a)(2) 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 proposed at § 484.58(a)(3) to require that the HHA consider the availability of caregivers 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. We proposed at § 484.58(a)(4) to require that the patient and caregiver(s) must be involved in the development of the discharge plan, and informed of the final plan. Furthermore, in order to incorporate patients and their families in the discharge planning process, we proposed at § 484.58(a)(5) to require that the discharge plan address the patient's goals of care and treatment preferences.

For those patients who are transferred to another HHA or who are discharged to a SNF, IRF, or LTCH, we proposed at § 484.58(a)(6) 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.

As required by the IMPACT Act, HHAs must take into account data on quality measures and resource use measures during the discharge planning process. We also proposed at § 484.58(a)(6) 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. We received many public comments on these proposed requirements for HHAs and we refer readers to section II.F of this final rule for a summary of those comments and our responses.

In addition, we proposed at § 484.58(a)(7) 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. We also proposed to require that the evaluation be included in the clinical record. We proposed 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.

Comment: Several commenters strongly supported the proposed requirements at § 484.58, "Discharge Planning." Commenters stated that these new requirements put patients and their needs at the center of the discharge process. They also stated that standardization would improve the process of transitioning between care settings, reduce

patient confusion, and improve compliance with discharge instructions. Additionally, other commenters were pleased to see the requirement to ensure that the discharge goals, preferences, and needs of each patient are identified. Other commenters requested specific clarifications of potentially ambiguous terms, such as “active partner,” “preventable readmissions,” and “effective transfers.” However, many commenters expressed concern regarding the burdens that would be imposed upon HHAs, should the proposed requirements become final, particularly because they believe there is no evidence that engaging in the extensive discharge process that we proposed would improve patient safety, HHA-physician communications, or post-HHA care delivery. The proposed role of the physician in discharge planning was of particular concern to many commenters. Some commenters supported the idea of involving the physician, but stated that they believed that in most instances the HHA would be in a better position to develop the patient's discharge plan because physicians are not always familiar with the community resources available in the communities that serve their patient. Commenters requested flexibility in the degree of physician involvement in establishing the discharge plan of care. In addition, many commenters did not support the proposed requirements. Commenters stated that if the provision were finalized as proposed, it would require a substantial amount of communication time for both HHAs and physicians, imposing significant burden upon both entities. HHAs voiced concern with the involvement of primary care physicians, whom they believe are often difficult to contact, and whom they believe do not want to be involved with a patient’s home health care if ordered by a different physician. Commenters recommended that only a discharge order from the primary care physician be required, and that the physician should receive a copy of the

discharge summary to follow-up with the patient as appropriate. Another commenter suggested that the proposed language be modified to allow physician discretion as to their involvement in the discharge planning process. Additionally, a commenter suggested that with the increasing number of "patient-centered medical home" situations, the person most suitable to be involved in the home health discharge planning would not be a physician, but rather a case manager, care coordinator or mid-level provider working under the overall direction of a physician.

Response: While we appreciate the support for this proposed requirement, we are sensitive to the burden and practicality concerns raised by commenters. It was not our intent to impose a process that may not align with current HHA processes or may be otherwise unduly burdensome. It was also not our intent to potentially strain HHA-physician relationships. We agree that this issue warrants further study and a better developed evidence base before we proceed further with rulemaking. We also agree that the proposed terminology lacked clarity in a manner that could make surveying for compliance difficult and potentially inconsistent.

Additionally, many of the areas addressed in the proposed HHA discharge planning requirements were subsequently addressed in a January 13, 2017 final rule in the **Federal Register**, titled "Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies" (82 FR 4504), referred hereinafter as "HHA CoP final rule", creating concerns regarding potential regulatory duplications that should be avoided. For example, the final HHA CoP final rule requires HHAs to communicate with all relevant parties, including physicians who are involved in the patient's HHA plan of care, whenever there are revisions related to the plan for patient discharge

(§ 484.60(c)(3)(ii)). We believe that this requirement, which was put into place following publication of the Discharge Planning proposed rule, accomplishes the goal of HHA-physician communication regarding discharge. As such, we believe that this separate discharge planning requirement is no longer necessary, and we are withdrawing the proposal at § 484.58(a)(2) 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 are also withdrawing the majority of the other general discharge planning requirements proposed in § 484.58(a), with the exception of those IMPACT Act requirements set forth in proposed paragraph (a)(6). We are committed to working with stakeholders to identify specific needs and concerns regarding discharge planning in the HHA care setting that may warrant future efforts, and to explore all options for achieving positive patient outcomes.

Comment: Commenters supported CMS's proposal that, for those patients who are subsequently transferred from a HHA to another HHA, SNF, IRF, or LTCH, the HHA should help patients assess the available providers.

Response: We appreciate the support for the requirement that HHAs assist patients when transferring to another post-acute care provider. We believe that recognizing patient preferences and assisting the patient with transfer options will support communication between the patient and the HHA, ultimately supporting patient informed decision making and improving patient care and satisfaction. We are finalizing this requirement as part of a more abbreviated discharge planning requirement at § 484.58(a).

Comment: A few commenters stated that the proposed rule does not adequately inform individuals of the full scope of their rights related to discharge and that the

proposed regulation should present the discharge requirements in terms of patient rights. Other commenters believe CMS should have added several of the provisions under the hospital Discharge Planning proposed rules to the home health proposed requirements. Some of the additional requirements the commenter suggested include:

- Require the HHA to specify who should be involved in designing, developing and coordinating the discharge planning process; and to involve social work staff and patient and family representatives.
- Assess a family caregiver's/support person's willingness to provide care.

Response: We appreciate the comments regarding HHA patient rights as related to the discharge process. We addressed patient rights in the HHA CoP final rule, which expanded our Patient Rights CoP. We believe that this Discharge Planning final rule, when combined with the requirements located in the HHA CoP final rule, adequately addresses the patient's right to be fully involved in all aspects of care planning, including the discharge plan, to the extent that the individual patient desires. This Discharge Planning final rule sets out the obligations of the HHA to both provide information to patients for selecting additional post-acute care services, and to provide important patient care-related information to follow-up care providers. As described earlier, we are not finalizing the proposed discharge planning process requirements of § 484.58(a), with the exception for those IMPACT Act requirements set forth in proposed paragraph (a)(6). As this requirement is not being finalized, it is not appropriate to specify those disciplines that must be involved in developing the process within each HHA. With regard to the suggestion that CMS should mandate that HHAs assess a family caregiver's/support person's willingness to provide care, this issue was also addressed in the HHA CoP final

rule (82 FR 4530 and 4581). In the HHA CoP final rule we implemented a new requirement that HHAs must assess a caregiver's willingness and ability to provide care as part of the comprehensive patient assessment.

Comment: Some commenters recommended that CMS require HHAs to ensure that the patient and caregiver receive discharge education and a copy of the discharge summary. Commenters also suggested that CMS should mandate the content of discharge instructions, including contact information for the receiving practitioner, information regarding follow-up appointments, medication schedule and instructions to specific care needs and treatment, and contact information for the HHA clinical manager.

Response: With regard to the suggestion that CMS should mandate what discharge instructions must include, we agree, and as part of the HHA CoP final rule, we require that HHAs provide patients with key information, such as information regarding medications and services provided, throughout the patient's duration of home health care (§ 484.60(e)). We also require at § 484.60(d)(5) that HHAs ensure that patients and caregivers receive ongoing education and training regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge. This ongoing information to educate and engage patients in their care is designed to ensure patient activation during home health care and prepare patients for discharge by ensuring that patients and caregivers have the necessary knowledge and skills to continue performing necessary tasks after HHA discharge. In light of these requirements, we do not believe that it is necessary to duplicate requirements for discharge instructions.

Comment: A few commenters suggested that HHAs should be required to have a post discharge follow-up process when home health services end.

Response: Post discharge activities by a discharging HHA are not covered services under Medicare. As a result, CMS cannot make this a requirement; however, there is nothing to prevent the HHA from adding a post discharge follow-up process for patients as part of their own discharge process.

Comment: One commenter supported the proposal that requires HHAs to evaluate and revise a patient's discharge plan as needed, and recommended that the timeline for revisions to a discharge plan should be determined by each individual HHA. Conversely, another commenter stated that while they understood the intent behind the proposed language to revise the plan, it would not be realistic because there are many cases where the patient's condition changes quickly and dramatically without warning. According to the commenter, revising a discharge plan based on such a change, which could be temporary, would be wasteful. The commenter instead recommended requiring HHAs to cooperate with inpatient facilities requiring information about patients receiving emergency or unplanned inpatient care when contacted, or if agency personnel were aware a contact was planned or occurring.

Response: We thank the commenters for their comments on discharge planning. We agree that the proposed time frame may have been unrealistic in certain cases. Regarding the commenter's concerns of inappropriately using resources to begin discharge planning too early in the care timeline, we also believe that requiring a specific timeframe for initiating discharge planning in the HHA environment may result in an inefficient, overly burdensome regulation. Therefore, we are not finalizing the proposed

requirement to update the discharge plan each time the patient assessment is updated in accordance with the requirements of § 484.55(d). We will continue to monitor the available evidence regarding HHA discharge planning, and may reconsider the issue of discharge planning timeframes in the future. We agree that HHAs should provide necessary information to transfer providers. This requirement is already included in the clinical records requirement of the HHA CoPs at § 484.110(a)(6).

Comment: One commenter requested that we clarify that one way HHAs could demonstrate compliance with the proposed requirement to involve physicians in discharge planning is by documenting any outreach to the physician to coordinate his or her involvement.

Response: In light of the burden and practicality concerns described by commenters, we are not finalizing the requirements originally proposed at § 484.58(a)(2). In accordance with the requirements of the HHA CoP final rule at § 484.60(c)(3)(ii), HHAs must communicate with all physicians who are involved in the patient's HHA plan of care whenever there are revisions related to the plan for patient discharge. We agree with the commenter that one way the HHA can demonstrate compliance is to document the HHA's outreach to the physician(s) involved.

Comment: A few commenters requested that the HHA requirements mirror the hospital discharge requirements to the extent reasonable. The commenter stated the hospital CoP proposed language at § 482.43(c)(1), requires that a "registered nurse, social worker, or other qualified personnel must coordinate the discharge needs evaluation and development of the discharge plan." The commenters recommend that a comparable

requirement be included in the HHA CoPs, as it would help clarify the respective roles of HHA staff and the patient's physician.

Response: We appreciate the commenter's suggestion. Section 484.105(c) of the recently implemented HHA CoP final rule requires each HHA to have one or more clinical managers with responsibility for, among other things, coordinating patient care, making referrals, assuring that patient needs are continually assessed, and assuring the development, implementation, and updates of the individualized plan of care. Section 484.60(c) includes the discharge plan as part of the overall plan of care. Therefore, the current rules already require a clinical manager, who may be a physician, nurse, or licensed therapist, to be responsible for the discharge plan.

Comment: We received one comment related to the proposed language regarding caregiver support. The commenter stated that the HHA's primary consideration with regard to family caregivers is their willingness to provide services to an ill, disabled or frail elderly individual. The commenter went on to state that there needs to be consideration of whether the caregiver is able to provide the care, especially given other factors such as the caregiver's age and other possible limitations. The commenter recommended that CMS consider requiring health care providers to engage in a conversation and subsequently document that a family caregiver understands the follow-up services that will be most critical to the patient, is able and willing to assist with the provision of care, as well as what specific supports the family caregiver requests and needs. The commenter further recommended that, in discussions of what support a family caregiver may need, his or her economic resources should be taken into account.

Response: Issues of caregiver willingness and ability are already addressed as part of the comprehensive assessment requirements at § 484.55(c)(6). Additionally, HHAs must include caregiver education and training as part of the plan of care (§ 484.60(a)(2)(xiii)) and must provide that training (§ 484.60(d)(5)). We believe that these ongoing efforts to educate, train, and otherwise engage caregivers throughout the continuum of HHA care meet the needs of caregivers in preparing for discharge. Furthermore, in this rule we are finalizing a requirement that HHAs must provide necessary medical information to post-HHA care providers to ensure the safe and effective transition of care that supports the post discharge goals for the patient. The sharing of this information will facilitate identification of needs and preferences moving forward in the next care setting.

Comment: One commenter stated that the regulation should be specific in requiring that the updates envisioned in § 484.58(a)(1) include re-checking goals and preferences of the patient. Proposed § 484.58(a)(4) would require that the patient be informed of the "final" plan, and the commenter suggested that the patient should be informed of every version of the plan. Additionally, the commenter suggested that the regulation should require that the patient not only be informed of the discharge plan, but also be given a copy of the discharge plan and each revision.

Response: We appreciate the commenter's suggestions related to discharge plan updates and the rechecking of patient goals and preferences. Section 484.60(c)(3)(ii) of the current HHA CoPs require that any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, all physicians issuing orders for the HHA plan of care, and the patient's primary care practitioner or

other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any). We believe that this existing requirement for regular communication accomplishes a similar goal without being overly prescriptive regarding the format of communications. Therefore, we are not finalizing any additional regulations for this topic.

Comment: One commenter requested clarification regarding the term "clinical record." The commenter asked if the term "clinical record" is broader than the term "medical record." The commenter also asked if this would include everything that would also be part of the "medical record," and recommended that the final regulation substitute the term "individual's medical record" in place of "clinical record" for consistency.

Response: The term "clinical record" is the current language that is used in the HHA CoPs and is not broader than the term "medical record." We use the terms interchangeably as they relate to HHAs.

Final Decision: After consideration of the comments we received on the proposed discharge planning rule, we are not finalizing the requirements set forth in proposed § 484.58(a), with the exception of those IMPACT Act requirements set forth at proposed paragraph (a)(6). The IMPACT Act requirements are being finalized at § 484.58(a).

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

We proposed 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.

We proposed to include these elements in the discharge plan so that there would be 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 solicited comments on these proposed medical information requirements.

Comment: We received many comments related to the content of the discharge summary; however, there was a wide range of suggestions on what type and how many elements should be included in the summary. Below is a summary of the different suggestions commenters made:

Items to be added to the summary:

• Caregiver name, contact information, and capacity.

Items to be eliminated from the summary:

• Laboratory and diagnostic tests and results: They would not typically be part of the home health medical record. This information would be part of the medical record for the entity that ordered the services.

• Unique Device Identifier: The HHA would not likely have this information. This information would be part of the medical record where the device was implanted.

• Consultation with a state's Prescription Drug Monitoring Program (PDMP): Some states do not have a PDMP and it is not clear what practitioners would/could have

access to this data base. Practitioners with drug prescribing privileges are the only people who might find value from a PDMP.

Items to include in the discharge summary only if the HHA performed or facilitated (or otherwise could transmit the information without additional activity):

- Consultation results and procedures: Only require inclusion of consultations and procedures that the HHA performed. The HHA would not have as part of their medical record consultation results and procedures performed by other facilities.

- Immunization: Only require reporting immunizations the HHA has provided.

Items to revise:

- Smoking status: Modify to include reporting of any significant adverse health behaviors rather than limiting the information to smoking.

- Any other information necessary: This provision should add "as determined necessary by the HHA."

- Current care plan, including goals and latest physician orders: The commenters noted that the proposal seemed redundant with the following required elements:

++ Course of illness/treatments.

++ Patient's goals and treatment preferences.

Items to be added:

- Diet.

- Name of the provider (facility, physician and advanced practice nurse) who will continue to provide care following discharge from home health care.

- Contact information for the HHA that provided the care.

- Name of any community-based social service provider known to be continuing service for the patient or from whom the patient may seek future assistance, such as Meals-on-Wheels, companion programs, housing programs, etc.
- Information on upcoming health-related appointments. These would include, but not be limited to, physician appointments, community social services and supports (for example, Meals-on-Wheels), non-medical home health, adult day care, outpatient therapy, and mental health follow-up appointments.
- Pharmacy, DME/oxygen, emergency response system or other vendor contact information (contact persons' names, phone numbers, and fax numbers).
- Instructions for patients and caregivers on what to do if unexpected symptoms or events occur. It may involve contacting a physician or behavioral health counselor or calling the home health agency office.

Furthermore, many commenters questioned the usefulness of much of the proposed minimum information that would be included in the transfer or discharge summary, as compared to the burden of compiling all of the required information. A few commenters stated that the intent of the discharge summary was good; however, there should be some allowances for the clinician to be able to give a succinct picture of the patient condition. Commenters stated that these requirements will take time to compile, delaying the ability to summarize pertinent succinct information timely. Other commenters stated that CMS should develop streamlined alternatives to the proposals, particularly the discharge summary requirements. Another commenter requested clarification as to whether CMS would only require that HHAs provide discharge or transfer summaries to other providers, not patients. It was suggested that CMS require

the information be sent to the physician responsible for the home health plan of care, in addition to the receiving facility or health care practitioner, which would ensure that the physician who established the home health plan of care has information to continue to be involved in the patient's care at a later time, as necessary. However, another commenter believed it may not be necessary to forward such information to the health care practitioner. The commenter recommended that the language be changed to reflect that the information be sent to the receiving facility and made available, upon request, to the health care practitioner.

Response: We appreciate the wide array of comments related to the proposed requirement at § 484.58(b). The disparate nature of the comments lead us to conclude that, at this time, there is no clear consensus regarding the minimum information that should be shared from one HHA to another health care provider in order to assure patient health and safety. We also note that there is a lack of a well-developed evidence base to identify best practices in the transfer of information from an HHA to another health care provider. Establishing a specific list of information that must be shared from an HHA to another health care provider creates a risk of simultaneously overburdening HHAs with elements that are not applicable and leaving out elements that are critical to assuring a safe and effective care transition in any given situation. The impracticality and potential ineffectiveness of such a list of mandatory discharge or transfer summary elements developed in the absence of public consensus and evidence-based practices would not improve patient care and safety, nor would it assure the efficient use of HHA resources. Therefore, we are not finalizing a list of requirements related to the content of the discharge summary. Rather, we are finalizing a requirement that HHAs must send all

necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care. This broad, flexible requirement allows HHAs to tailor the exchange of information to the exact circumstances and needs of the care transition in order to support the patient's post-discharge goals.

Sending the discharge summary to the follow-up care practitioner or facility was set forth in the HHA CoPs final rule, and we did not propose to modify that requirement. It is just as important for the receiving health care practitioner to be sent the discharge information as it is for the HHA to receive such information from the patient's previous care provider. For continuity of care and a smooth transition from the HHA, we believe the discharge summary will provide invaluable information to the receiving practitioner/facility to continue to meet the patient's care needs.

We continue to believe that there are instances in which the receiving health care practitioner or facility would request additional information beyond that which the HHA provided in the discharge or transfer summary, such as the patient's actual plan of care. However, we agree with commenters that this information is not automatically necessary for each and every HHA patient discharge or transfer. Therefore, we have modified this requirement, as finalized at § 484.58(b)(2), to require HHAs to comply with requests for additional essential clinical information as may be necessary for treatment of the patient that are made by the receiving facility or health care practitioner. We believe that this change will assure that receiving facilities and practitioners have access to this information as needed, while not overburdening HHAs to preemptively provide such a

potentially large volume of information that may not be helpful to receiving practitioners and facilities.

Comment: One commenter stated that not all of the information in the plan of care and latest physician orders may be relevant at the time of discharge. CMS should allow the agency to determine which parts of the plan of care and physician orders are appropriate to be included in the discharge summary.

Response: We appreciate the commenters' suggestions to allow the HHA to determine, which parts of the plan of care and physician orders are appropriate to include in the discharge summary. As noted above, we have revised the requirement at § 484.58(b) to include only that medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences that is necessary to ensure the safe and effective transition of care, as identified by the HHA. We have replaced the proposed requirement that an HHA must send a copy of the plan of care with a requirement at § 484.58(b)(2) that an HHA must comply with requests from receiving providers for additional essential clinical information as may be necessary for the treatment of the patient, which may include providing the receiving practitioner or facility with a copy of the plan of care. We believe that this revised approach balances the need for information exchange with the need for succinct, targeted communication among providers.

Comment: Many commenters acknowledged that the requirements are intended to provide safe and efficient follow-up care planning. However, commenters believe that the information required in the proposed rule would involve volumes of documents, many of which would be duplicative of information provided in an EHR. One

commenter acknowledged that the required elements for the discharge or transfer summary are aligned with the Common Clinical Data Set specified in the 2015 Edition of the health IT certification criteria. The commenter stated that the most direct method to comply with the proposed discharge summary requirements is for agencies to utilize an interoperable EHR that could meet the Common Clinical Data Set specification that is supported by the Consolidated Clinical Document Architecture (C-CDA) and the 2015 Edition certification criteria for §170.315(b)(1) (Transitions of Care) and §170.315(b)(9) (Care Plan). Another commenter added that EHR vendors may be able to assist in the provision of this information because the commenter believes that the vendors can help streamline and standardize the exchange process for every discharge and transition. However, another commenter stated that current home care electronic medical record systems do not support the creation of a transfer summary and will require time to accomplish. In addition, the commenter stated that several of the data elements may not apply to every patient situation. The commenter added that simply stating 'not applicable' could be construed in a medical record as incomplete, unavailable, or unknown and that only the known, applicable data be included in the transfer summary, and that CMS should allow for a grace period to come into compliance with these new requirements.

Response: We appreciate the comments regarding the discharge summary and the EHR. We understand that HHAs may face significant challenges in electronically exchanging the list of items originally set forth at proposed § 484.58(b). In light of these challenges and for the reasons set forth above, we are not finalizing a list of items to be included in every discharge or transfer summary. We do believe that, over time, HHAs and all providers should continue to work toward fully implementing an EHR that is

capable of collecting, sending, and receiving patient data to improve care transitions. We would expect acute care providers that collect data electronically to provide this information in an electronic format to HHAs that have the capacity to receive such electronic information and incorporate it into their EHRs. We also believe the HHA vendors can help streamline and standardize the exchange process for every discharge and transition.

Comment: One commenter explained that transfers between HHAs are often initiated by the patient and patient transfers are unknown to the agency until the agency receives a call from the patient's new provider. The commenter further noted that patients rarely consult with their current agency on the quality of a competitor. The commenter questioned how HHAs will be held accountable for compliance in instances when the HHA is unaware of a patient's transfer or pending transfer. The commenter recommended that language regarding transfers to a different HHA be changed to refer to only planned transfers in which the current HHA is involved.

Response: We expect all HHAs to meet the requirements of this final rule. In accordance with the existing clinical records requirements at § 484.110(a)(6), HHAs must send a completed transfer summary within 2 business days of a planned transfer, if the patient's care will be immediately continued in a health care facility. If the transfer was unplanned, the HHA must send a completed transfer summary within 2 business days of becoming aware of the unplanned transfer, only if the patient is still receiving care in a health care facility at the time when the HHA becomes aware of the transfer. There are additional requirements related to sending information following patient discharge, also located at § 484.110(a)(6), that do not directly pertain to patient transfers.

Final Decision: After consideration of the comments we received on the proposed rule, we are finalizing § 484.58(b) with the following modifications:

- Revising § 484.58(b)(1) to require that, instead of a specified list, the HHA must send necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences to the receiving facility or health care practitioner to ensure the safe and effective transition of care.
- Revising § 484.58(b)(2) to require the HHA to comply with requests for additional necessary clinical information made by the receiving facility or health care practitioner, which may include items such as a copy of the patient's current plan of care or latest physicians' orders.

Miscellaneous Comments (Proposed § 484.58)

Comment: We received one comment requesting that occupational therapists be listed as part of the discharge planning team needed to perform discharge assessment and planning. Another commenter suggested that CMS consider adding the role of the "Discharge Intensivist." The commenter stated that the role can be an assistive role handled through a "Discharge Health Coach (DHC)" to effectuate a discharge plan. The role of a DHC would be an assistive role that is trained as a discharge coach. The commenter stated that this kind of collaborative communication doesn't currently exist in a home health agency, and needs to be created for the purpose of meeting the goal of effective discharge planning and execution.

Response: We appreciate the comment on various professionals who may be involved in the discharge planning process. HHAs are permitted to involve any and all professionals, as appropriate to each patient's discharge plan. While we have removed

the specific discharge planning requirements of proposed § 484.58(a), HHAs will continue to engage in discharge planning as part of overall care planning set forth in § 484.60. We encourage HHAs to utilize the expertise of all professionals involved in a patient's care, as well as any specialty services that may benefit HHAs and their patients.

Comment: One commenter stated that we should include transitions to acute care, along with transitions to PAC facilities in setting out requirements for HHA discharge planning. The commenter added that the proposed regulations provide requirements for HHAs when discharging individuals to other PAC providers and believe that individuals would benefit from similar planning and information sharing when HHAs must send the individual back to acute care. The commenter recommended that documentation, including the individual's health history with previous functional status, current functional status, goals and preferences, be provided to the hospital in order to expedite care and discharge planning in the hospital setting.

Response: We agree with the commenter's suggestion that HHAs can be integral in transitioning the individual back to acute care and that discharge summary documentation should be provided to expedite care and subsequent additional discharge planning in the hospital setting. The requirement at § 484.58(b), "Discharge or transfer summary content", requires the HHA to send necessary medical information to the receiving facility or health care practitioner. This applies to patients discharged to an acute care setting.

Comment: One commenter stated that HHAs should not be allowed to discharge patients who have an ongoing need unless they are discharging to a Medicaid consumer direction program. The commenter states that it is too easy for HHAs to discharge people

who are difficult, or even those with difficult family members or those that require visits at inconvenient hours.

Response: We appreciate the commenter's views and concerns. As finalized in the HHA CoP final rule, HHAs may only discharge patients for certain specific reasons. We believe that the requirements set forth at § 484.50(d) appropriately regulate HHA discharge and transfer policies to prevent inappropriate discharges. Specifically, § 484.50(d)(5)) requires that if the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired, the HHA must take numerous steps to resolve the problem and provide advance notice that a discharge is being considered. The HHA must advise the patient, representative (if any), the physician(s) issuing orders for the home health plan of care, and the patient's primary care practitioner or other health care professional (if any), who will be responsible for providing care and services to the patient after discharge from the HHA, that a discharge for cause is being considered. The HHA must also make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or situation. Furthermore, the HHA must provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care. Finally, the HHA must document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records.

Comment: A commenter stated that if a patient went from an HHA to a SNF there should be an independent review to see if the HHA did everything possible to prevent this outcome, including interviewing the patient. If the HHA was found to have

caused the SNF admission directly or by omission, the HHA should have to pay for re-institutionalization.

Response: At this time we do not require HHAs to track the patients at discharge. In addition, we do not have the ability to bill the HHA for re-institutionalization of the patient. This comment is beyond the scope of this final rule.

Comment: One commenter requested that we require specific criteria for the discharge of people who are homeless. The commenter stated that HHAs should be prohibited from refusing to serve clients in homeless shelters or hotels serving as homes. The same commenter also suggested that there should be someone to call who has the power to effect immediate intervention, if a patient is being discharged without instructions or without services being set up. They add that they are regularly called to try to assist people who have been discharged and they have no written instructions, or poorly written instructions, and they tried to protest or ask for additional information from the HHA without recourse or solution.

Response: We appreciate the comments related to the discharge of patients who are homeless, and the lack of planning and discharge instructions for such patients. The HHA CoPs require HHAs to work with the patient and caregiver, including communication with the patient's physician(s), when updating the discharge plan. The HHA is also already required to educate and instruct the patient regarding his or her care responsibilities on an ongoing basis to prepare for ultimate discharge. Because education and training to facilitate discharge will have been provided during the entire course of HHA care, thus preparing patients and caregivers for discharge, this final rule does not include a requirement for discharge instructions. This final rule does not include a

requirement for HHAs to establish follow-up services once a patient is discharged, as this is the role of the patient's primary care or other follow-up care practitioner. This final rule requires HHAs to send the patient discharge summary to the patient's follow-up health care provider to ensure that this essential information is communicated as the patient transitions care providers. Furthermore, this final rule requires HHAs to provide additional medically necessary information upon request from a receiving facility or practitioner. We believe that these requirements address these important concerns.

Comment: One commenter suggested that CMS should require utilization of independent living centers instead of nursing homes for moderately functioning patients. The commenter stated that it is cheaper for the government and it gives patients an opportunity to improve on their physical and mental functions and hopefully be reintegrated into the community. Additionally, the commenter added that independent living centers should develop relationships with HHAs and give these patients services beyond room and board. These centers are considered homes to patients whose family members are unable to care for them.

Response: We thank the commenter for their suggestion to require utilization of independent living centers instead of nursing homes for moderately functioning patients. However, these comments are beyond the scope of this rule and cannot be addressed.

Final Decision: After consideration of the miscellaneous comments, we are not making any additional revisions to § 484.58.

G. Critical Access Hospital Discharge Planning (Proposed §§ 485.635(a)(3)(viii) and 485.642)

Sections 1820(e) and 1861(mm) of the Act require CAHs participating in Medicare and Medicaid to meet certain specified requirements. We have implemented these provisions in 42 CFR part 485, subpart F, "Conditions of Participation: Critical Access Hospitals (CAHs)".

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. Minimally, what was required under the former EACH/RPCH program was adopted for what is now the 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. Also, the CoPs at § 485.635 require a CAH to develop and keep current a nursing care plan for each patient receiving inpatient services.

Given the IMPACT Act mandate, we proposed CAH discharge planning requirements. In the Discharge Planning proposed rule, we solicited comments on the timeline for implementation of the proposed CAH discharge planning requirements (80 FR 68139). We discuss the comments we received and our responses in section II.B of this final rule.

We proposed to develop requirements in the form of five standards at § 485.642 and one additional standard at § 485.635. 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 proposed to require that the CAH provide specific

discharge instructions, as appropriate, for all patients.

We proposed that each CAH's discharge planning process ensure that the discharge needs of each patient were identified and resulted in the development of an appropriate discharge plan for each patient.

Comment: Many commenters agreed with including CAHs in the discharge planning requirements. The commenters stated that requiring CAHs to have a discharge planning CoP would assist in providing a systematic approach to effective and quality patient care. A commenter stated that the inclusion of patient considerations is important and they appreciate CMS's inclusion of statements about the importance of geography. One commenter stated that they support the requirement that the discharge planning policies and procedures be developed with input from the CAH's professional health care staff, nursing leadership as well as other relevant departments and be reviewed and approved by the governing body. The commenter further stated that this is the current process in many CAHs. However, one commenter stated that the current incentive programs to discourage readmissions already address many of the factors included in our proposed discharge planning requirement, such as the need for non-health care factors, and, therefore, this requirement is not necessary.

Response: We appreciate the commenters' support for the CAH discharge planning requirements and we appreciate being made aware that many CAHs have developed policies and procedures for discharge planning. We are finalizing a revised version of the proposed CAH discharge planning requirements that focuses on patient outcomes and provides implementation flexibilities.

Comment: Several comments stated that the CAH discharge planning

requirements should be identical to the hospital discharge planning requirements.

Response: The CAH discharge planning requirements are intentionally very similar to those of the hospital discharge planning requirements. However, there are some necessary differences as a result of some of the challenges that are unique to CAHs, including their rural location, small size, and limited resources.

Comment: One commenter suggested that the requirements under § 482.43(f)(1) (regarding transfer to post-acute care services) apply to CAHs.

Response: Section 4321 of the BBA amended the discharge planning requirements to require that the discharge planning evaluation indicate the availability of home health services provided by individuals or entities that participate in the Medicare program. Section 4321(a) of the BBA requires that hospitals, in their discharge planning evaluation, provide a listing regarding the ‘‘availability of home health services.” This has been implemented in the hospital CoPs under § 482.43(c)(8). Section 926 of the MMA further amended 1861(ee) of the Act to include information regarding SNFs that participate in the Medicare program; the IMPACT Act added section 1899B of the Act further requires that CAHs provide patients with LTCH, IRF, HHA, and SNF data on quality measures and data on resource use measures. Section 4321 of the BBA did not apply to CAHs, given their rural location and the limited number of PAC providers in their geographic regions. We believe that extending this requirement to CAHs by regulation places an unnecessary burden on them. While CAHs are not required to include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs, they are required to, like hospitals, assist patients, their families, or their caregivers or support persons in selecting a PAC provider. CAHs must do so by using and sharing data that includes but

is not limited to HHA, SNF, IRF, or LTCH data on quality measures and resource use measures. Although CAHs are not required to include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs, there is nothing prohibiting them from doing so.

Proposed § 485.642

We received no substantive comments on the introductory language of this provision. We are finalizing it with only minor stylistic amendments that do not affect the substance of the rule. As revised, the CAH must have an effective discharge planning process that focuses on the patient's goals and preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from CAH to post-discharge care, and reduce the factors leading to preventable CAH readmissions.

1. Design (Proposed § 485.642(a))

We proposed at § 485.642(a) to establish a new standard, "Design," to require a CAH to have policies and procedures for discharge planning that have been developed with input from the CAH's professional health care staff and nursing leadership, as well as other relevant departments. The policies and procedures would be approved by the governing body or responsible individual and be specified in writing. We did not receive any comments on this standard. However, upon further review, we believe that this requirement may be too process oriented and too prescriptive as written to finalize and that a further revision to this requirement for CAHs is warranted. We therefore, are not finalizing this requirement as proposed and we refer readers to section II.C.3 of this final

rule for a detailed discussion of this decision.

2. Applicability (Proposed § 485.642(b))

We proposed 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 expect to be discharged or transferred to a hospital within 96 hours after admission to the CAH. We proposed 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 health care staff and approved by the governing body or responsible individual.

Comment: A number of commenters agreed with the proposal to broaden the categories of patients who would be evaluated for post-discharge needs. Several stated that they believed the inclusion of these categories of patients was necessary for effective transition from acute settings to post-acute settings. However, the majority of commenters expressed concern over the undue burden that they believe would result from this proposed change. Many stated that they believe that the current evaluation requirement is effective for screening and targeting high-risk patients who have true discharge needs. A number of commenter stated that they already routinely screen certain categories of outpatients, such as observation patients, and that automatically

requiring discharge plans for patients in these categories would shift resources away from those patients most in need of discharge plan.

Response: As with hospitals, we agree with commenters that the requirement needs to be scaled back in its scope and applicability to a more flexible requirement. We therefore, are not finalizing the requirements at proposed § 485.642(b). Instead, we are finalizing requirements at § 485.642(a) introductory text and (a)(2), respectively, that would require that a CAH's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified, as well as for other patients upon the request of the patient, patient's representative, or patient's physician. In addition, at § 485.642(a)(2), a discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-hospital extended care services, and home health services, and must also determine the availability of those services.

Final Decision: Similar to hospitals, after consideration of the comments we received on the proposed rule, we are revising proposed § 485.642(b), and finalizing as § 485.642(a) introductory text and (a)(2), to require that the CAH's discharge planning process identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning, and must provide a discharge planning evaluation for those patients so identified, as well as for other patients upon the request of the patient, patient's representative, or patient's physician. A discharge planning evaluation must include an

evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-CAH extended care services, and home health services; such evaluation must also determine the availability of those services.

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

We proposed 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 proposed 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 proposed 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 that the process be 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-related needs of the patient 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 noted 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 proposed at § 485.642(c)(3) that the CAH's discharge planning process 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 proposed at § 485.642(c)(4) that the practitioner responsible for the care of the patient be required to be involved in the ongoing process of establishing the discharge plan.

We proposed 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 proposed to require that CAHs must consider the availability of and access to non-health care services for patients, which could include home and physical environment modifications, transportation services, meal services, or household services, including housing for homeless patients. In addition, we encouraged 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 proposed 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 proposed 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 proposed 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 would be taken into account throughout the entire discharge planning process.

We proposed at § 485.642(c)(8) to require that CAHs assist patients, their families, or caregivers in selecting a PAC using IMPACT Act quality measures. This provision is part of our IMPACT Act requirements and is discussed later in this preamble.

We proposed 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 would ensure that appropriate arrangements for post-CAH care were 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 proposed to require that the evaluation be included in the medical record. The results of the evaluation would 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 proposed 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 would have to 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 were responsive to patient discharge needs.

Comment: Several commenters stated that the rural location and small size of CAHs pose difficulties for them in ensuring that they have the appropriate staff available to implement the discharge planning requirements. As a result, the commenters

expressed that it would present significant burden to CAHs if all proposed patients were required to have discharge planning within 24 hours of admission or registration. Commenters suggested that CAHs be permitted to use telehealth options to fulfill some of the requirements due to the issues they face related to staffing shortages.

Response: The requirements do not prohibit the use of telehealth services to meet the discharge planning requirements so long as all of the discharge and telehealth requirements are met. It is not uncommon for CAHs to use telehealth services in the provision of patient care services given their rural location and their resultant staffing difficulties. In addition, we are finalizing our requirement at § 485.642(a) to state that any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel. As such, CAHs are not limited to using social workers or case managers to meet these requirements. The CAH has the flexibility to determine and identify other personnel qualified to coordinate the discharge planning evaluation and development of the discharge plan. We expect that the CAH will identify personnel qualified to conduct this activity as part of its discharge planning process.

Comment: One commenter stated that many rural Americans live in areas with limited health care resources, restricting their available options for care, including post-acute care options. As such, the commenter suggested that we allow rural hospitals to consider the impact of incomplete quality reporting data for PAC providers in the local community or where limited resources are available to collect the data, especially where geographic considerations are especially important to the patient and caregivers.

Response: We appreciate the constraints under which rural hospitals and CAHs

must operate. Since the goal is to provide quality care for patients, we expect the providers to consider all information that is available and pertinent to a given location. The regulation will require rural providers to assist patients and their families, or their caregivers/support person in selecting a PAC by using and sharing data. The data that are provided should be pertinent to the patient's goals of care and treatment preferences. We expect that any available data will be shared with the patient and various support individuals, and that the provider will explain the issues or constraints with the data and advise the patient on seeking PACs outside of the local community. We also expect that providers in rural and frontier areas will extend their list of PAC providers to areas outside of the local community if necessary.

Comment: One commenter stated that the requirement to utilize data on quality measures and data on resource use measures could be utilized to discourage the use of CAH swing beds in rural communities. Since the CAH swing bed program does not have to report data on its performance, referring facilities will list CAH Swing Bed on their referral list delivered to patients, but would have no data to include on the list. The commenter suggested that we require referring facilities to note on their discharge provider list that CAH swing beds are not required to report data similar to freestanding SNFs.

Response: The CAH's responsibility is to advise and assist patients with their choices based on quality data and the patient's goals of care and treatment preferences. As such, we do not believe that any provider will be disadvantaged with this requirement.

Final Decision: After consideration of the comments received on the proposed rule, both those discussed above and the comments discussed in conjunction with the

parallel hospital provisions, we are finalizing and redesignating § 485.642(c) with the following modifications:

- Revising and redesignating § 485.642(c)(2) under § 485.642(a) to eliminate the 24-hour time frame requirements and to state that the CAH must identify at an early stage of hospitalization all patients who are likely to suffer adverse health consequences upon discharge if there is no adequate discharge planning.

- Revising and redesignating § 485.642(c)(6) under § 485.642(a) to state that the patient and caregiver/support person(s), as applicable, must be involved in the development of the discharge plan, and informed of the final plan to prepare them for post-CAH care.

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

We proposed 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 was referred to a PAC provider or supplier, the discharge instructions would be provided to the PAC provider/supplier.

At § 485.642(d)(2) we proposed that instructions on post-discharge care include, but not be limited to, instruction on post-discharge care, including instruction on durable medical equipment, if applicable, 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 proposed to require that the instructions include:

- Written information on warning signs and symptoms that may indicate the need to seek immediate medical attention.

• Prescriptions for medications that would be 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).

• 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.

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. Therefore, we proposed 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 reminded CAHs to provide this information in a manner that complied 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 recommended that CAHs consider the use of "teach-back" techniques during discharge planning and upon providing discharge instructions to the patient.

We proposed 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 instructions and medication regimens and improve patient safety and satisfaction. We proposed 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 noted the importance of ensuring that CAHs follow-up, post-discharge, with their most vulnerable patients, including those with behavioral health conditions.

Final Decision: After consideration of the comments received on the proposed rule (as discussed under the hospital section), we are not finalizing § 482.43(d). We are redesignating the proposed requirement in § 485.642(d)(3) as § 485.642(b) and we are eliminating the specific timeframe requirements. Section 485.642(b) provides that the CAH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

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 proposed 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 would have to 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 directives, 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, and documentation as applicable, including a copy of the patient's discharge instructions, the discharge summary, and such information and documentation pertaining to current diagnoses, course of illness/treatment, laboratory results, procedures, functional status, and the patient's goals of care and treatment preferences, to ensure a safe and effective transition of care that supports the post-discharge goals for the patient.

Final Decision: After consideration of the comments we received on the proposed rule, as discussed in the hospital section at section II.C.7 of this final rule, we are finalizing § 485.642(e) with modifications. We are revising and redesignating § 485.642 as follows:

- Removing proposed § 485.642(a) and (b), and replacing these standards with revisions and redesignating as § 485.642(a) titled "Discharge planning process." The final standard at § 485.642(a) incorporates and combines provisions of the current hospital discharge planning requirements (that are statutorily required for hospitals) with revised provisions from the proposed requirements at § 485.642(c).
- Removing proposed § 485.642(c), (d), and (e) and replacing these standards with revisions and redesignating as § 485.642(b) titled "Discharge and transfer of the patient and provision and transmission of the patient's necessary medical information."

The final standard at § 485.642(b) incorporates and combines revised provisions from the proposed requirements at § 485.642(c), (d), and (e).

- Revising § 485.642(b) to state that the CAH must provide and send the patient's necessary medical information to the receiving post-acute care services provider, if applicable, along with all necessary medical information .

III. Provisions of the Final Regulations

In this final rule, we are adopting § 482.13(d)(2) from the Hospital Innovation proposed rule with only two minor clarifying revisions. We are moving the phrase, "including current medical records," to the beginning of the paragraph and by adding the word, "and," before the phrase, "within a reasonable timeframe," so that this part of the provision now states that the patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame.

Additionally, we are adopting some of the provisions of the Discharge Planning proposed rule with the following extensive revisions and reorganizations of the final requirements as discussed above:

- Revising §§ 482.43 and 485.642, respectively, to now require that the hospital (or CAH) must have an effective discharge planning process that focuses on the patient's goals and preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge

planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from hospital (or CAH) to post-discharge care, and reduce the factors leading to preventable hospital (or CAH) readmissions.

- Removing § 482.43(a), (b), and (c), respectively and § 485.642(a), (b), and (c), and replacing these standards with revised and redesignated standards at §§ 482.43(a) and 485.642(a), respectively, entitled "Discharge planning process" for each section. The final standards at §§ 482.43(a) and 485.642(a) incorporate and combine provisions of the current hospital discharge planning requirements (that are statutorily required for hospitals) with revised provisions from the proposed requirements at §§ 482.43(c) and 485.642(c), respectively.

- Removing § 482.43(c), (d), and (e) for hospitals and § 485.642(c), (d), and (e) for CAHs, and replacing these standards with revised and redesignated standards at §§ 482.43(b) and 485.642(b), respectively, entitled "Discharge and transfer of the patient and provision and transmission of the patient's necessary medical information" for each section. The final standards at §§ 482.43(b) and 485.642(b) incorporate and combine revised provisions from the proposed requirements at § 482.43(c), (d), and (e) for hospitals and § 485.642(c), (d), and (e) for CAHs, respectively. Sections 482.43(b) and 485.642(b) state that the hospital (or CAH) must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other

outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

- Redesignate and finalize proposed § 482.43(f) at § 482.43(c) without modification.

HHAs:

- Revising § 484.58 to remove requirements related to 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.
- Revising § 484.58(a) to remove paragraphs (a)(1) through (5) and (7).
- Revising § 484.58(a) to combine paragraph (a)(6) with the introductory statement for paragraph (a).
- Revising § 484.58(b)(1) to require the HHA to send necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences to the receiving facility or health care practitioner to ensure the safe and effective transition of care.
- Revising § 484.58(b)(2) to require the HHA to comply with requests for additional information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner, which may include items such as a copy of the patient's current plan of care or latest physicians' orders.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection

should be approved by OMB, section 3506(c)(2)(A) of the 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 solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). Responses to comments received for this section can be found in section VI "Regulatory Impact Analysis" of this final rule.

In the estimates that follow in this section of the preamble and in the Regulatory Impact Analysis (RIA), we estimate hourly costs. Using data from the Bureau of Labor Statistics (BLS) for May 2017, we have estimates of the national average hourly wages for all professions (these data can be seen at https://www.bls.gov/oes/2017/may/oes_nat.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.

A. ICRs Regarding Hospital Discharge Planning (§ 482.43)

The requirements at § 482.43(a)(8) (and all similar requirements set out at § 485.642(a)(8) for CAHs and § 484.58(a) for HHAs), which correspond to the requirements of the IMPACT Act, are exempted from the application of the PRA pursuant to section 1899B(m) of the Act. Therefore, we are not required to estimate the public reporting burden for information collection requirements for these specific elements of the final rule in accordance with chapter 35, title 45 of the United States Code. Nor are we required to undergo the specific public notice requirements of the PRA. Therefore, the estimates we provide in the RIA section of this final 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 gave 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 final rule from PRA analysis. We further note that these 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.

Whenever a patient is discharged or transferred to another facility, § 482.43(b) requires hospitals to send necessary medical information to the receiving facility at the time of transfer. 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 (at

§ 482.43(d) prior to finalization of this rule). Overall, we believe that almost all of the 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 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 rule.

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

We are finalizing a new CoP at § 484.58 that will require HHAs to develop and implement an effective discharge planning process.

The requirements at § 484.58(a) correspond to the requirements of the IMPACT Act, and are exempted from the application of the PRA pursuant to section 1899B(m) of the Act. Therefore, we are not required to estimate the public reporting burden for information collection requirements for that specific element of the final rule in accordance with chapter 35, title 45 of the United States Code. Nor are we required to undergo the specific public notice requirements of the PRA. Therefore, the estimates we provide in the RIA section of this final 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.

At § 484.58(b), we are establishing another new standard, "Discharge or transfer summary content," to require that the HHA send necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of

care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.

We are also including a requirement at § 484.58(b)(2) for HHAs to comply with requests for additional information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

To meet both the requirements to assist patients in selecting follow-up post-acute care providers and to develop a discharge or transfer summary for each patient, we estimate that it will take an HHA approximately 10 minutes (0.167 hours) per patient. Thus, for the 12,600 HHAs, we estimate that complying with this requirement will require 3,006,000 burden hours (18 million patients x 0.167 hours) at an approximate cost of $213.4 million (3,006,000 burden hours x $71 average hourly salary for a registered nurse (RN)).

The cost of sending the discharge summary to the patient's next source of health care services, as required by § 484.110(a)(6), was accounted for in the HHA CoP final rule (82 FR 4504) issued in January 2017 and accompanying collection of information package (OMB Control Number 0938-1299). As this issue has already been addressed in separate rulemaking, and as we are not making any changes to the requirements for sending the discharge or transfer summary in this final rule, we are not modifying the existing burden estimates.

We believe that providing additional information, upon request, to follow-up care providers is a standard practice for 90 percent of HHAs. Likewise, we believe that providing such documents upon request may represent a new burden for those 10 percent of HHAs who are not already engaging in such information sharing practices. Based on

information provided by commenters, who indicated that follow-up care providers often do not want to receive the large volume of information found in a copy of a patient's plan of care, we do not believe that follow-up care providers will request additional documentation for most discharged or transferred patients. For purposes of this analysis only, we assume that follow-up care providers and facilities will only request additional documentation for 10 percent of an affected HHA's discharged or transferred patients.

(18 million patients x .1 affected HHAs = 1,800,000 patients in affected HHAs)

(1,800,000 patients in affected HHAs x .1 discharged or transferred patients who require additional documentation = 180,000 patients)

Based on the above calculations, we estimate that up to 180,000 requests for additional information will be made upon effected HHAs. We estimate that it will take 15 minutes to process each request and either print and fax, or otherwise send the additional requested documentation, for a total of 45,000 hours per year (180,000 requests x .25 hours per request) at a cost of $1,485,000 (45,000 hours x $33 general office clerk hourly rate). Thus, we estimate compliance with this new CoP costs HHAs approximately $215 million annually ($213.4 million to assist patients in selecting follow-up post-acute care providers and to develop a discharge or transfer summary for each patient + $1.5 million to process and send additional requested information).

The information collection request related to the home health agency CoPs (OMB Control Number 0938-1299) will be revised and sent to OMB.

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 revisions will 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 finalizing new CAH discharge planning requirements.

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 CAH discharge planning requirements mirror those for hospitals, we believe that CAHs, like hospitals, are essentially already performing many of the 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).

The new requirements at § 485.642(a) require that the CAH's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to

suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

We also are requiring that each CAH's discharge planning process must:

- Be made on a timely basis to ensure that appropriate arrangements for post-CAH care will be made before discharge and to avoid unnecessary delays in discharge, a discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-CAH services, including, but not limited to, hospice care services, post-CAH extended care services, and home health services, and non-health care services and community based care providers, and must also determine the availability of the appropriate services as well as the patient's access to those services;
- That the discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative);
- Upon the request of a patient's physician, the CAH must arrange for the development and initial implementation of a discharge plan for the patient;
- That any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel;

- That the CAH'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; and
- That the CAH 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.

The requirement at § 485.642(a)(8) in particular corresponds to the requirements of the IMPACT Act, and is exempted from the application of the PRA pursuant to section 1899B(m) of the Act. Therefore, we are not required to estimate the public reporting burden for information collection requirements for that specific element of this final rule in accordance with chapter 35, title 45 of the United States Code. Nor are we required to undergo the specific public notice requirements of the PRA. Therefore, the estimates we provide in the RIA section of this final 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.

Whenever a patient is discharged or transferred to another facility, § 485.642(b) requires 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 § 485.642(b)(1) through (6). 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 necessary medical information included under § 485.642(b)(1). Thus, we believe that CAHs are already following most of these requirements and therefore we will not be assessing any additional burden for this section beyond our estimate in the RIA of the one-time cost to CAHs to modify their policies and procedures in order to ensure that they are meeting the requirements of this rule.

V. Regulatory Impact Analysis

A. Statement of Need

All major government regulations should undergo periodic review to ensure that they do not unduly burden regulated entities or the American people, and reflect current knowledge as to regulatory effects. In recent years, we have revised the CoPs and CfCs to reduce the regulatory burden on providers and suppliers. In doing so, we identified obsolete and burdensome regulations that could be eliminated or reformed to improve effectiveness or reduce unnecessary reporting requirements and other costs, with a particular focus on freeing up resources that health care providers, health plans, and states could use to improve or enhance patient health and safety. This final rule focuses on reforms to discharge procedures that will enhance patient health and safety by filling gaps, while providing appropriate flexibility.

In line with HHS' goals to improve interoperability between patients and their health care providers, we are finalizing certain discharge planning requirements for hospitals (including LTCHs and IRFs), HHAs, and CAHs as well as finalizing the hospital patients' rights requirement regarding patient access to medical records. We are also finalizing the requirements of the IMPACT Act for hospitals, HHAs, and CAHs. We believe that these

final requirements will empower patients to be active participants in the discharge planning process and will help them to make informed choices about their care, which will lead to more competition, lower costs, and improved quality of care. Furthermore, the IMPACT Act requirements will give 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 who are well informed of their choices of high-quality PAC providers may reduce their chances of being re-hospitalized.

We believe these final requirements will also encourage interoperability, which allows patients to have access and full control over their medical records and encourages the seamless exchange of patient information between health care settings. Ultimately, these final requirements will ensure that a patient's health care information follows them after discharge from a hospital or PAC provider to their receiving health care facility, whether that be their primary care physician or a SNF.

Furthermore, discharge planning is an important component of successful transition from hospital 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), SNF or nursing home, LTCH, 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 (as appropriate) 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 by focusing requirements on cases where risks are highest and by allowing providers to focus resources on such cases.

Executive Order 13563 on Improving Regulation and Regulatory Review 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." This final rule applies that mandate to discharge planning.

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.

The importance of this retrospective review has been underscored by recent findings on health care delivery problems related to hospitalization, including discharge and readmissions, indicating 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.).

The comments and our responses to the Collection of Information (COI) Requirements and the Regulatory Impact Analysis (RIA) sections are as follows.

Comment: Many commenters stated that we underestimated the implementation cost for the proposed requirements for hospitals and, particularly, CAHs. They stated that many of the proposed requirements were burdensome and overly prescriptive and that we underestimated the cost of hiring new staff, training existing staff, and updating and changing EHRs.

Response: We have significantly scaled back our proposed requirements and are finalizing a more limited set of discharge planning and other requirements as explained throughout the preceding preamble discussion. There are more than a dozen areas where this final rule limits and reduces costs along the lines suggested by commenters. For example, commenters presented evidence that our proposed requirements would impose unreasonable burdens on HHAs in obtaining involvement of patients' physicians in discharge planning, and on hospitals in obtaining and using PDMP information. We greatly appreciate the detailed comments we received and the regulatory improvements that they recommended. In the responses that follow, we address primarily those

comments focusing specifically on the collection of information requirements and regulatory impact analysis sections of this final rule, or involving particularly costly or cost-saving issues. These are only a fraction of those dealing with costs or burdens that are already addressed in the preamble.

Comment: Regarding the changes to the HHA requirements, one commenter pointed out that we did not estimate the cost of training clinicians to understand and effectively put into practice the new policies and procedures. The commenter also noted the need for CMS to calculate the cost for changes to an HHA's electronic health records to incorporate the revisions to the rule here.

Response: We have not estimated training costs since we believe that training related to changes in policies and procedures or to improve implementation of existing policies and procedures is an ongoing process in HHAs. In this final rule we have focused on ways to make minor modifications to existing processes that can be implemented with minimal training. For the costs to an HHA's electronic health records, we have removed the list of specific information that must be included in the discharge or transfer summary. The current HHA CoPs at § 484.110 already require HHAs to send a discharge or transfer summary to the receiving provider, so the software used by HHAs to complete this task already exists. As HHAs are already required to prepare and send a transfer or discharge summary, we do not believe that there are substantial additional costs, not already accounted for in section IV "Collection of Information Requirements" of this final rule that should be included in our analysis.

Comment: One commenter requested that we calculate the costs for the time required for an HHA physical therapist to create exercise and activity recommendations for patients recovering from orthopedic or neurologic injuries at home.

Response: We do not believe that such costs are related to the new requirements finalized here, so we have not included estimates in the COI or RIA sections.

Comment: Several commenters disagreed with our estimates on the amount of time that it would take an HHA to develop a discharge plan per patient. One commenter stated that we have underestimated the time required of an RN or physical therapist to complete the HHA standards finalized here. The commenter believes that it would take 10 to 15 minutes, not 5, for a nurse or therapist to assemble all of the information, review the medication list for accuracy, review the goals for completeness, and draft the recommendations for care following discharge.

Response: We agree with the commenters and have made the relevant adjustments in section IV "Collection of Information Requirements" of this final rule to use an estimate of 10 minutes. We chose 10 minutes because we believe that there will be many relatively uncomplicated cases where 5 minutes would be sufficient, and relatively few where 15 minutes would be necessary, especially since the final rule provisions streamline and reduce the burden compared to the more onerous provisions in the proposed rule that these commenters reviewed. We note that the proposed rule would have shown total information collection burden costs of over $550 million annually had this estimate been more realistic in the Discharge proposed rule.

Comment: Numerous commenters argued that we should add additional occupational specialties to the hospital discharge planning team. Among the categories

recommended were physical therapy, nutrition, mental health, dental, durable medical equipment, and others. These commenters argued that some patients would have specialized needs in such categories of subsequent care.

Response: We disagree with the commenters and have added none of the recommended categories. This would have added immensely to the complexity and cost of the discharge planning process. It is the function of the discharge experts already used by each hospital (usually including an expert RN or social worker) to identify such needs, as pertinent to each patient, and tailor the discharge plan to that patient.

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), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

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 an RIA that to the best of our ability presents the costs and benefits of the rulemaking. This final rule will create both one-time and annual costs for hospitals, CAHs and HHAs. The financial costs are summarized in Table 1.

Table 1: Section-by-Section Economic Impact Estimates

Provider/Supplier and Description of Proposed Provisions	Number of Affected Entities	Estimated Costs ($ millions)
Annual:		
Hospitals (§ 482.43)	4,900	*
HHAs: Discharge Planning Process(§ 484.58)	12,600	213.4
HHAs: Requests for Information (§ 484.58)	12,600	1.5
Total		214.9
One-time:		
Hospitals (§ 482.43)	4,900	17.7
CAHs (§ 485.642)	1,353	1.9
HHAs (§ 484.58)	12,600	10.8
Cost of reviewing final rule	18,853	16.1
Total		46.5

*Less than $1 million

C. Anticipated Effects

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

We have accounted for the regulatory impact of these changes through the analysis of costs contained in the ICR sections previously mentioned in this final rule. We believe these estimates encompass most additional burden on hospitals, CAHs, and HHAs, with the exception of the following one-time costs to review the revised requirements and adjust internal procedures to assure compliance, particularly in the area of providing quality information to patients for multiple providers of post-discharge services. Any burden associated with the changes to the CoPs not accounted for in the ICR section or in the RIA section was omitted because we believe it would constitute an 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 websites Hospital Compare, Nursing Home Compare and Home Health Compare, as well as other public and private websites and their own knowledge of local providers, and presumably many or most use this information as appropriate to counsel patients.

Hospitals will need to review their current policies and procedures and update them so that they comply with the modified requirements, which will be a one-time burden on each hospital. We estimate that an administrator will spend 8 hours on this activity for a total of 8 hours per hospital at a cost of $1,680 (8 hours x $210 for an administrator's hourly salary cost), together with an RN or equivalent for an additional 8 hours at a cost of $568 (8 hours x $71 for an RN salary cost). Lawyer and physician time will also be used. We assume 4 hours of legal time at $136 an hour for a cost of $544 and 4 hours of physician time at $203 an hour for a cost of $812. For all hospitals to comply with this requirement, we estimate a total one-time cost of approximately $17.7 million (4,900 hospitals x $3,604 ($1,680 plus $568 plus $544 plus $812 = $2,780)).

We are establishing a new standard at § 484.58(a), "Discharge planning process," to require that the HHA's discharge planning process provide certain information to those

patients who are discharged or transferred to another post-acute care provider in order to assist patients and families in selecting a provider that meets the patient's needs and goals. HHAs will need to review their current policies and procedures and update them so that they comply with the requirements in § 484.58(a), which will be a one-time burden on the HHA. We estimate that this will require an administrator using the average hourly salary of a medical and health services manager as determined by the BLS, doubled to account for fringe benefits and overhead. We estimate that the administrator will spend 8 hours on this activity for a total of 8 hours per HHA at a cost of $856 (8 hours x $107 for an administrator's hourly salary). For all HHAs to comply with this requirement, we estimate a total one-time cost of approximately $10.8 million (12,600 HHAs x $856).

The requirement at § 485.642(a)(8), which is associated with the IMPACT Act, will require CAHs to review their current policies and procedures and update them so that they comply with the new requirements, which will be a one-time burden on the CAH. We estimate that the administrator will spend 8 hours on this activity for a total of 8 hours per CAH at a cost of $856 (8 hours x $107 for an administrator's hourly salary cost), together with an RN or equivalent for an additional 8 hours at a cost of $568 (8 hours x $71 for an RN salary cost). The total burden hours are 21,648 (16 hours x 1,353 CAHs). For all CAHs to comply with this requirement, we estimate a total one-time cost of approximately $1.9 million (1,353 CAHs x ($856 plus $568)).

Our estimates of the effects of this regulation are subject to significant uncertainty. While HHS is confident that these changes 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, HHAs, and CAHs in these matters.

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. The Discharge Planning proposed rule was estimated to have total first year costs of $454 million (80 FR 68148), and annual costs thereafter of $396 million. As previously discussed, both these numbers would have been about $100 million higher if the time needed for HHA discharge functions had been estimated more realistically. This final rule, in contrast, has estimated total first year costs of $262 million and annual costs thereafter of $215 million. This reduction of costs by more than half reflects some downward re-estimates, but mainly our efforts to remove overly prescriptive and costly process requirements that had originally been proposed. It also reflects the many comments we received pointing out ways to improve the rule. These changes show both the benefits of the public comment process under the Administrative Procedure Act, and the focus of CMS in developing final rules in complying with the goals of the laws and Executive Orders previously discussed, especially Executive Orders 12866, 13563 and 13771.

2. Effects on small entities

The Regulatory Flexibility Act (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 will be affected by our rules are small entities as that term is used in the RFA. The great majority of hospitals and most other health care 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 final rule will cost affected entities approximately $215 million a year. Virtually all of these costs will impact HHAs. Total annual revenues of HHAs are approximately $100 billion a year (see Anne B. Martin et al, "National Health Care Spending In 2017," *Health Affairs*, January 2019) and there are about 12,600 HHAs. Hence, the average cost per HHA would be about $17,000, about one fifth of one percent of annual revenues. All HHAs are not "average" in size, and about 2,000 of them have fewer than 10 employees. But our annual cost estimates are directly proportional to number of patients, so costs to even the smallest HHAs would be well under one percent of annual revenues. 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 rule will not have a significant economic impact on a substantial number of small entities, and certify that a Final Regulatory Flexibility Analysis is not required. Regardless, this RIA and the remainder of the preamble together meet the RFA requirements for such an analysis. In particular, we call attention to the many places in the non-RIA sections of the preamble where public comments helped us to analyze particular options and reject those that would have unnecessarily placed far higher burdens on HHAs or other entities. Specifically, our rejection of options that would have required consultations with health care professionals of many

kinds, rather than consultations only as necessary for a particular patient, avoided very substantial costs on small entities.

Under the proposed rule costs to hospitals would have exceeded $100 million annually. We note that quite apart from the gross amount of such compliance costs 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 any hospital 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. Under this final rule hospital and CAH costs have been essentially eliminated, and hence we anticipate no impact on 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 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. For the preceding reasons, we have determined that this rule will 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 2019, that threshold is approximately $154 million. Although this rule does not technically require HHAs to incur the costs unless they participate in Medicare, as a practical matter few HHAs could remain in business without participating in Medicare and these costs exceed this threshold in early years before subsequent payment increases take increased costs into effect. Mandated spending for CAHs, in contrast, is largely reimbursed on a cost basis and would not count as an unfunded mandate even in early years. This RIA and the other preamble sections together meet the UMRA requirements for analysis of the costs to these providers.

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, preempt state law, or otherwise have federalism implications. This final rule will not have a substantial direct effect on state or local governments, preempt state law, or otherwise have federalism implications.

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, however, unable to quantify either the volume or dollar value of these 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 and Medicaid 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 rule. Nonetheless, the number of patients potentially benefitting is significant.

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 exist on the effectiveness of these requirements compared to the normal effects of good medical practice. The changes that will be implemented by this 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 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.[1]

4. Regulatory Review Cost Estimate

One of the costs of compliance with a final rule is the necessity for affected entities to review the rule in order to understand what it requires and what changes the entity will have to make to come into compliance. The particular staff involved in such a review will vary from provider to provider. We believe that a good approximation for a range of staff would be a person such as a medical and health service manager. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is $107 per hour, including overhead and fringe benefits https://www.bls.gov/oes/2017/may/oes_nat.htm. Assuming an average reading speed, we estimate that it will take approximately 4 hours for each of the staff involved to review this final rule and its relevant sections and that on average two persons on staff will engage in this review (more for hospitals and CAHs and fewer for HHAs). For each entity that reviews the rule, the estimated cost is therefore $856 (4 hours each x 2 staff x $107 per hour each). Therefore, we estimate that the total cost of reviewing this rule, assuming two reviewers per affected entity, is $16.1 million ($856 x 18,853 affected entities).

D. Alternatives Considered

As we previously stated in this final rule, some of these provisions are mandated under the IMPACT Act; therefore, no major alternatives were considered for those

[1] Kim J. Verhaegh et al, "Transitional Care Interventions Prevent Hospital Readmissions for Adults with Chronic Illnesses," *Health Affairs*, 33, no. 9 (2014):1531 through 1539.

provisions. For the other provisions, we considered a wide range of alternatives, but determined that none of them would result in substantial benefits at a reasonable cost.

For all provisions, we attempted to minimize unnecessarily prescriptive methods or procedures, and to avoid any unnecessarily costly and burdensome requirements. Of particular importance for this final rule, the public comments were exceptionally useful in identifying weak or unjustified provisions in the proposed rule as well as in identifying alternatives. These alternatives are discussed throughout the preamble. The three most costly alternatives that we considered and rejected were requiring specific post-discharge procedures for every patient, requiring that discharge plans be prepared and revised on specific hourly schedules for every patients, and requiring direct individual consultation with a wide range of health care professionals for every patient.

For the alternative of specific post-discharge follow-up procedures, we concluded that the range of procedures was so great (including 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 we could devise no reasonable or practicable requirement that would sensibly apply to all or most patients. Of course, we encourage providers to use follow-up procedures they find cost-effective for particular categories of patients.

The alternative of requiring specific hourly deadlines for beginning a discharge plan would have created immense costs due simply to the myriad circumstances of hospital patients, as described by many examples in the comments. Likewise, commenters identified no consequential benefits, and major costs, were we to impose

discharge planning on ambulatory care not even involving an overnight hospital stay, and involving such low risk procedures as providing tooth fillings, cataract surgery, and carpal tunnel surgery.

The third alternative arose from comments from a number of professional associations and individual professionals asking that we mandate use of their particular professions in discharge planning for every patient. These would also have been very costly to impose. As previously discussed, we found no reason to believe that routinely using these professionals in all discharge planning would have provided consequential benefits over and above benefits from selective consultation where indicated by patient-specific conditions.

E. Cost to the Federal Government

When these requirements are finalized, CMS will update the interpretive guidance, update the survey process, and provide training. In order to make these three changes, we anticipate initial, one-time federal startup costs at 4 or 5 person-years, and hence total cost of approximately 1 million dollars including overhead costs and fringe benefits. CMS plans to rely on CMS program management resources to support these costs. The continuing annual costs (survey process-recertifications, enforcement by states or accredited organizations, appeals, AO) will not change from current levels.

F. Accounting Statement

As required by OMB Circular A-4 (available at https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf), 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 10 years as an estimating horizon, and used low and high estimates that are 25 percent lower or higher than our primary estimate. We note that the accounting statement for the proposed rule showed annual costs of about $420 million in 2015 dollars, and that the changes made in this final rule have cut that cost in half. This reduction is even larger in real terms because public comments showed us that the Discharge proposed rule would have been about $100 million annually more costly than estimated.

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--Annualized Monetized Costs of Discharge Planning to Medical Care Providers	220	170	280	2017	7%	2019-2028
	220	170	280	2017	3%	2019-2028
Transfers	None					

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

G. Regulatory Reform Analysis under Executive Order 13771

Executive Order 13771, titled Reducing Regulation and Controlling Regulatory Costs, was issued on January 30, 2017 and requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." This final rule imposes costs and therefore is considered to be a regulatory action under Executive

Order 13771. We estimate that this rule will impose annualized costs of approximately $175 million discounted relative to 2016 over a perpetual time horizon.

H. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq*.), the Office of Information and Regulatory Affairs designated this rule as a major rule, as defined by 5 U.S.C. 804(2). As such, this rule has been transmitted to the Congress and the Comptroller General for review.

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, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 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: 42 U.S.C. 1302, 1395hh, 1395rr, and 1395lll unless otherwise noted.

2. Section 482.13 is amended by revising paragraph (d)(2) to read as follows:

§ 482.13 Condition of participation: Patient's rights.

* * * * *

(d) * * *

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

* * * * *

3. Section 482.43 is revised to read as follows:

§ 482.43 Condition of participation: Discharge planning.

The hospital must have an effective discharge planning process that focuses on the patient’s goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-

discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to preventable hospital readmissions.

(a) Standard: Discharge planning process. The hospital's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-hospital extended care services, home health services, and non-health care services and community based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(4) Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

(5) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(6) 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.

(7) 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.

(8) The hospital must assist 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.

(b) <u>Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information</u>. The hospital must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-

discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

(c) Standard: Requirements related to 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) and (b) 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

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

Authority: 42 U.S.C. 1302 and 1395(hh) unless otherwise indicated.

5. Section 484.58 is added to read as follows:

§ 484.58 Condition of participation: Discharge planning.

(a) Standard: Discharge planning. An HHA must develop and implement an effective discharge planning process. 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.

(b) Standard: Discharge or transfer summary content. (1) The HHA must send all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, to the receiving facility or health care practitioner to ensure the safe and effective transition of care.

(2) The HHA must comply with requests for additional clinical information as may be necessary for treatment of the patient made by the receiving facility or health care practitioner.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

6. The authority citation for part 485 is revised to read as follows:

Authority: 42 U.S.C. 1302 and 1395(hh).

7. 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) Policies and procedures that address the post-acute care needs of patients receiving CAH services.

* * * * *

8. Section 485.642 is added to read as follows:

§ 485.642 Condition of participation: Discharge planning.

A Critical Access Hospital (CAH) must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from the CAH to post-discharge care, and reduce the factors leading to preventable CAH and hospital readmissions.

(a) Standard: Discharge planning process. The CAH's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-CAH care will be made before discharge and to avoid unnecessary delays in discharge.

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-CAH services, including, but not limited to, hospice care services, post-CAH extended care services, home health services, and non-health care services and community based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(4) Upon the request of a patient's physician, the CAH must arrange for the development and initial implementation of a discharge plan for the patient.

(5) Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(6) The CAH'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.

(7) The CAH 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.

(8) The CAH must assist 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 CAH 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.

(b) <u>Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information</u>. The CAH must discharge the patient, and also

transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

Dated: August 20, 2019.

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Seema Verma,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: September 17, 2019.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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