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

Summary of Final Rules

On September 30, 2019 the Centers for Medicare & Medicaid Services (CMS) published in the *Federal Register* (84 FR 51836) a final rule that addresses discharge planning requirements for hospitals, critical access hospitals (CAHs), and post-acute care (PAC) settings. Within this final rule, CMS also finalized a provision from the "Hospital Innovation" proposed rule (81 FR 39448), [1] which addresses a patient's right to access his or her own medical information from a hospital. Unless otherwise noted, the rules are effective November 29, 2019.

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I. Introduction and Background

A. Overview

CMS describes the rationale for discharge planning and its role in reducing avoidable hospital readmissions and patient complications. Patients' post-discharge needs are frequently complicated and depend on numerous factors, thus requiring a significant level of ongoing planning, coordination and communication among health care practitioners and facilities as well as well as with the patients themselves and their caregivers. Transitions to PAC settings and to the home present increased risks to patients that need to be recognized and accounted for in the discharge planning process. Further, hospitals and CAHs need to improve their focus on patients

[1] The Hospital Innovation proposed rule is formally known as the "Medicare and Medicaid Programs; Hospital and Critical Access Hospital (CAH) Changes to Promote Innovation, Flexibility, and Improvement in Patient Care" (81 FR 39448). CMS states that it is continuing to consider comments on the remaining portion of the Hospital Innovation proposed rule and will respond to those comments when it finalize that rule in future rulemaking.

with psychiatric and behavioral health problems, including substance use disorders, in the discharge planning process.

The provisions of the IMPACT Act of 2014 (Pub. L. 113-185) require hospitals, including but not limited to acute care hospitals, CAHs and certain PAC providers (including long-term care hospitals (LTCHs), inpatient rehabilitation facilities (IRFs), home health agencies (HHAs), and skilled nursing facilities (SNFs)), to take into account quality measures and resource use measures to assist patients and their families during the discharge planning process. CMS says that 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, potentially reducing their chances of being re-hospitalized.

B. Legislative History

CMS summarizes the provisions of the IMPACT Act and its activities to implement various requirements of the Act. Section 2 of the 2014 law added section 1899B to the Social Security Act. Subsection (i), which addresses discharge planning, requires the modification of the Conditions of Participation (CoPs) and subsequent interpretive guidance applicable to PAC providers, hospitals, and CAHs at least every 5 years, beginning no later than January 1, 2016. These provisions require that PAC providers, hospitals, and CAHs take into account quality, resource use, and other measures under subsections (c) and (d) of section 1899B in the discharge planning process. The purpose of this final rule is to implement these discharge planning requirements by modifying the discharge planning or discharge summary CoPs for hospitals, CAHs, IRFs, LTCHs, and HHAs.

CMS notes that 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, are classifications of hospitals. Because all classifications of hospitals are subject to the same hospital CoPs, these PAC providers (including freestanding LTCHs and IRFs) are also subject to the revisions to the hospital CoPs.[2] Compliance with these requirements will be assessed through on-site surveys by CMS, state survey agencies or accrediting organizations (AOs) with CMS-approved Medicare accreditation programs.

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

A. General Comments

Overall, commenters were generally in favor of standardizing and modernizing the discharge planning requirements for hospitals, including LTCHs and IRFs, HHAs, and CAHs. Most commenters, however, disagreed with certain, specific proposed discharge planning requirements and believed that the proposed requirements were too burdensome or overly prescriptive. Other commenters believed that the requirements did not go far enough to protect patients, and that without better protections some discharges from hospitals would lead to readmissions or

[2] Discharge planning requirements for SNFs are addressed in a final rule, "Medicare and Medicaid Programs; Reform of Requirements for Long-Term Care Facilities" (81 FR 68688).

unnecessary emergency department visits shortly after discharge. Commenters also asked for clarification about which specific provider types would be required to comply with the discharge planning CoPs. Other commenters provided specific comments about the sub-regulatory interpretive guidance.

In response, CMS believes 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 increase interoperability across the care continuum. In addition, it believes the changes made in the final rule are significantly less burdensome than its initial proposed discharge planning requirements. CMS also clarifies that all classifications of hospitals except CAHs are regulated under part 482 of its regulations, are subject to the same set of hospital CoPs. Specifically, this includes 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.[3] CMS indicates that the interpretive guidance will be updated once publication of the final rule, and notes that the development of this guidance, as a sub-regulatory process, is not required to be circulated for public comment.

B. Discharge Planning Requirements of the IMPACT Act of 2014

CMS finalizes and redesignates the proposed discharge planning requirements of the IMPACT Act of 2014 at §§482.43(c)(8) and 485.642(c)(8) as §§482.43(a)(8) and 485.642(a)(8), respectively, without modification. CMS also finalizes and redesignates the requirements in proposed §484.58(a)(6) as §484.58(a), without modification. These provisions are as follows:

- Provisions at §482.43(a)(8) 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. The hospital must ensure that the PAC data on quality measures and on resource use measures aligns with the patient's goals of care and treatment preferences.

- Similar provisions at §484.58(a) apply to HHAs. For those patients who are transferred to another HHA or who are discharged to a SNF, IRF, or LTCH, §484.58(a) requires 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. The HHA would have also have to ensure that it provides 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.

[3]Inpatient psychiatric units located in a hospital, (as opposed to psychiatric hospitals) are specialized units within a larger hospital or CAH, and are not 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. Therefore, these discharge planning requirements apply to inpatient psychiatric units located within a hospital or a CAH.

- Provisions for CAHs at §485.642(a)(8) are similar to the requirements for hospital and HHAs, described above.

Commenters were generally supportive of the IMPACT Act's goals to standardize data amongst PAC providers, but most requested clarification on the specifics of the proposed IMPACT Act discharge planning requirements for hospitals, HHAs, and CAHs. In addition, most commenters asked CMS to clarify what data sources hospitals would be expected to use and where these data sources would be available. Many were also concerned about how these data would be disseminated and interpreted. Several commenters asked for clarification on how providers can assist patients in choosing a PAC provider without improperly steering the patient to certain providers.

In response, CMS notes that 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. In addition, CMS states that since the publication of the proposed rule in 2015, CMS has implemented quality and resource use measures into its quality reporting programs (QRPs); this includes measures for the domains of functional status, skin integrity, the incidence of major falls, and the resource use and other measures which are publicly available on the various IRF, SNF, LTCH, and Home Health Compare websites. With respect to concerns about patient steering, CMS believes compliance with the revised CoP and the fraud and abuse laws, including the physician self-referral law and federal anti-kickback statute, is achievable. CMS states 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. CMS reminds providers that they must document all such interactions in the medical record.

C. Implementation

CMS solicited comments on the timelines for implementation of the discharge planning requirements for HHAs and CAHs. Many commenters recommended a delay in the implementation or effective date of the final discharge planning requirements for all providers. Recommendations for implementation timeframes or delays included, among others, 1 to 5 years; piloting discharge requirements before finalizing them, and phasing in the requirements. Most commenters also suggested delaying the effective date of the discharge planning requirements of the IMPACT Act until quality reporting data is publicly available.

In response, CMS believes that most hospitals and CAHs have discharge planning processes in place and these providers will be well prepared to implement the final discharge planning requirements. CMS also states that in light of the significant streamlining of the final discharge planning requirements for HHAs, it does not believe an additional delay of the effective date for the implementation of the final discharge planning requirements for HHAs, including the Impact Act requirements, is necessary.

Thus, CMS finalizes the following timeframes for implementation of the final discharge planning requirements:

- 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.

Sixty-days after publication of this final rule is November 29, 2019.

D. Prescription Drug Monitoring Programs (PDMPs)

In the discharge planning proposed rule, CMS 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. Given the potential benefits of PDMPs, CMS 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. CMS also solicited comments in the proposed rule on the use of PDMPs in the medication reconciliation process.

CMS indicates that it received a large number of comments on this issue. The majority of commenters strongly disagreed with establishing a requirement for providers to consult with their state's PDMP, indicating that such a requirement would be burdensome and time consuming for providers and their prescribing practitioners. In addition, many commenters pointed out that access to PDMPs varies widely by state and the data contained in their individual state's PDMP is often incomplete, out of date, provides limited access or access that is slow. Others noted that their states did not have a PDMP, while others indicate their state's PDMP statutes were not enacted to assist discharge planning.

In response, CMS clarifies that this was a solicitation of comments and not a proposal as some commenters had incorrectly assumed. CMS agrees 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. It encourages, however, practitioners to utilize strategies and tools, such as PDMPs, to the extent permissible, to reduce prescription drug misuse. It also notes that since the publication of the proposed rule, additional states have adopted statewide PDMP programs and reminds 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, CMS proposed to clarify that the patient has the right to access their medical records upon request within a reasonable time frame (30 days, though CMS expects most requests would be fulfilled in less time). The hospital must furnish the information in the format requested by the individual if readily available, or a readable hard copy or other form agreed to by the individual and the facility if the medical records are not readily available in the form requested by the individual. Complaints about untimely responses or other difficulties can be made at: https://www.hhs.gov/hipaa/filing-a-complaint/index.html. CMS also

refers readers to provisions of the Promoting Operability Program that requires providers to provide other information to patients under shorter timeframes: https://www.hhs.gov/hipaa/for-professionals/faq/2051/under-the-ehr-incentive-program-participating-providers/index.html.

CMS' use of the 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. Rather, CMS is using well-understood terms that are consistent across all of its regulations.

Comments were generally supportive of the proposed policy. CMS is finalizing the proposal with minor editorial changes for clarity.

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

CMS proposed to revise discharge planning introductory paragraph to require that a hospital have an effective discharge planning process that focuses on the patients' goals and preferences. The plan must prepare 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 reducing the likelihood of hospital readmissions. Comments were generally supportive of the policy. CMS is finalizing the proposal with minor editorial changes for clarity.

3. Design (Proposed §482.43(a))

CMS proposed to require hospital medical staff, nursing leadership, and other pertinent services to provide input in the development of the discharge planning process. In response to comments that found the proposal to be overly prescriptive, CMS is not finalizing it. The proposed requirement that the governing body periodically review the discharge planning process is finalized. However, CMS is not establishing the proposed minimum 2-year time period for review of the discharge planning process although it believes such a review should occur at least that often.

In response to a comment, CMS recommends providers follow the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care, which provide guidance on providing discharge planning instructions in a culturally and linguistically appropriate manner (https://thinkculturalhealth.hhs.gov/clas/standards).

4. Applicability (Proposed §482.43(b))

CMS proposed to apply the discharge planning process to all inpatients and several categories of outpatients. Public commenters objected to this proposal as unduly burdensome, suggesting it would divert resources from patients most in need of discharge planning. CMS agreed and is not finalizing the proposal.

The final policy requires that a hospital 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. The hospital must provide these patients with a discharge planning evaluation. A discharge planning evaluation must also be furnished upon request of the patient, the patient's representative, or the patient's physician. The discharge planning evaluation must include the patient's likely need for appropriate post-hospital services and the availability of those services.

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

CMS proposed to require 10 specific elements in the discharge planning process. However, numerous commenters objected that the proposal was overly detailed and prescriptive. In response to the comments, CMS significantly revised the proposed requirements to focus less on specific processes and prescriptive elements, and more on overall outcomes and flexibilities.

The final rule incorporates and combined 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:

- Hospitals will still be required to assess their discharge planning processes on a regular basis, which includes 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.
- Any required discharge planning evaluation or discharge plan must be developed by, or under the supervision of a registered nurse, social worker, or another appropriately qualified personnel.
- 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.
- 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.
- 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).
- The discharge plan must focus on the patient's goals and preferences and include the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to preventable hospital readmissions.
- 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.
- Requirements related to post-acute care services apply to patients whose discharge plan includes a referral to HHA services or transfer to a SNF, IRF, or LTCH.

CMS is not requiring hospitals to collaborate with community-based organizations in the final rule but encourages 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.

In addition, CMS does not believe that hospitals and CAHs should hold patients until a post-acute care bed is available, although it understands that sometimes hospitals hold patients until a bed is available at a corresponding post-acute care 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.

CMS refers readers to the following web links for more information about community organizations:

- https://www.medicaid.gov/medicaid/finance/downloads/no-wrong-door-guidance.pdf
- https://acl.gov/

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

CMS proposed detailed requirements for discharge planning for patients discharged home. Numerous commenters expressed overall disagreement with the proposed requirements as overly detailed and prescriptive. In response, CMS has removed the majority of the proposed requirements and significantly revised others.

The final rule indicates that the overall involvement of the patient and caregivers, as already set forth in regulations, 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.

CMS is 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. The hospital is furnished with the flexibility to effectively determine and align the pertinent patient information provided in the discharge plan based on the clinical judgment of the practitioners responsible for the care of the patient. Hospitals are required to transfer clinically appropriate discharge information to dialysis facilities, dialysis units, and nephrologists where applicable to the patient's post-hospital care. A patient referred for home health must be referred to a Medicare-participating HHA that serves the geographic area (as defined by the HHA) in which the patient resides. The patient may continue to use a previously used HHA as long as the HHA can continue to the meet the patient's needs.

The final rule further states that for patients that decline to participate in the discharge planning process or leave the hospital or CAH against medical advice, hospitals should document the patient's refusal in the patient's medical record.

In response to comments, the final rule also provides 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://thinkculturalhealth.hhs.gov/clas/standards
- http://www.teachbacktraining.org/

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

CMS proposed detailed requirements for discharge planning for patients transferred to other health care facilities, including that hospitals provide the information at the time of the patient's discharge and transfer to the receiving facility. Commenters generally found the list of required information to be overly prescriptive, excessively extensive, time consuming, duplicative, and burdensome. CMS agrees and indicates that it strives to promote successful transitions of care between health care settings and believes 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. In support of this goal, CMS provides links to continuity of care documents or universal transfer forms:

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

CMS continues to believe that hospitals and CAHs should be required to send certain necessary medical information to a receiving facility upon a patient's transfer but agrees with commenters that facilities should have discretion to send information that has the most "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 includes 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. CMS provides these as examples of information and not an exhaustive list of items CMS believes are critical to patient care.

The agency will 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) versus when it would not be appropriate to delay an emergency transfer waiting on the availability of a discharge summary. CMS further clarifies that in those hospitals and CAHs where multiple licensed and qualified practitioners are responsible for the care of the same

patient, delay of the discharge, and transfer or referral where applicable 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.

CMS supports the alignment with the Common Clinical Data Set (CCDS), which health care providers are electronically exchanging through the use of certified EHR technology (80 FR 62693). By finalizing the requirement to release certain medical information in accordance with all applicable laws, CMS is ensuring that the CoPs do not conflict with the CCDS requirements.

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

These requirements relate to furnishing a list of HHAs or SNFs that are available to the patient as part of the discharge planning process. CMS proposed to retain current provisions of the regulations and clarify that the PAC providers mentioned in the IMPACT Act, specifically LTCHs and IRFs (rehabilitation hospitals and rehabilitation units of hospitals and CAHs), are also subject to the proposed revision to the hospital CoPs.

For patients enrolled in managed care organizations, 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 hospital must also disclose any financial interest in a referred HHA or SNF.

The rule allows 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. For HHA, SNF, and dialysis services, a hospital can access a list from the CMS website (https://www.medicare.gov/) or develop and maintain its own list of HHAs and SNFs. 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. 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. Providing a list does not constitute a recommendation or endorsement by the hospital of the quality of care of any particular post-acute care provider. Post-acute care providers that do not meet all of the criteria for inclusion on the list are not required to be listed.

The hospital must not specify or otherwise limit the qualified providers or suppliers that are available to the patient. Hospitals are encouraged to provide any information regarding post-acute care 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 post-acute care provider's specialized services, CMS encourages that this information be provided to the patient as well as any culturally specific needs that the post-acute care providers are able to address (for example, the patient's foreign language needs, and their cultural dietary needs or restrictions). CMS finalized the proposed requirements without modification.

F. Home Health Agency Discharge Planning (Part 484.58 Condition of Participation: Discharge Planning)

The current regulations at §484.110 require HHAs to prepare a discharge summary that includes the patient's medical and health status at discharge, include the discharge summary in the patient's clinical record, and send the discharge summary to the attending physician upon request. Under the proposed revision at §484.58, HHAs would be required to develop and implement an effective discharge planning process that focuses on preparing patients to be active partners in post-discharge care, provides an effective transition of the patient from HHA to post-HHA care, and reduces factors leading to preventable readmissions.

1. Discharge planning process (§484.58(a))

With one exception, CMS did not finalize the discharge planning requirements set forth in proposed §484.58(a). CMS finalizes the IMPACT Act requirements set forth at proposed paragraph (a)(6), now finalized at §484.58(a). Specifically, this provision requires 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.

CMS did not finalize the broader discharge planning requirements. Under its proposal, the HHA's discharge planning process would have been required to 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. Under proposed paragraph (a), the HHA's discharge planning process would have met the following (similar to hospitals):

> (1) The process would have to require regular re-evaluation of patients to identify changes that require modification of the discharge plan, in accordance with the provisions for updating the patient assessment at §484.55. It would have to be updated, as needed, to reflect these changes.
>
> (2) The physician responsible for the home health plan of care would have to be involved in the ongoing process of establishing the discharge plan.
>
> (3) The HHA would be required to consider caregiver/support person availability, and the patient's or caregiver's capability to perform required care, as part of the identification of discharge needs.
>
> (4) The patient and caregiver(s) would have to be involved in the development of the discharge plan, and informed of the final plan.
>
> (5) The discharge plan would have to address the patient's goals of care and treatment preferences.
>
> (6) For patients transferred to another HHA or discharged to a SNF, IRF, or LTCH, the HHA would be required 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 PAC quality

and resource use data. The HHA would have to ensure that the PAC data on quality measures and data on resource use measures was relevant and applicable to the patient's goals of care and treatment preferences. (HHAs could not, however, make decisions on PAC services on the patient's behalf.)

(7) 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 and needs; it would have to be included in the clinical record; and the results of the evaluation discussed with the patient or his/her representative. All relevant patient information would have to be incorporated into the plan to facilitate its implementation and to avoid unnecessary delays in the patient's discharge.

Most commenters expressed concern regarding the burdens that would be imposed upon HHAs, should these provisions become final. They believed that there is no evidence that engaging in such an extensive discharge process that CMS proposed would improve patient safety, HHA-physician communication, or post-HHA care delivery. Of particular concern for many commenters was the degree of physician involvement in establishing the discharge plan of care; commenters requested flexibility in the degree of physician involvement. In response, CMS states that it is sensitive to the burden and practicality concerns raised by commenters, and it was not its intent to impose a process that may not align with current HHA processes, be unduly burdensome, or potentially strain HHA-physician relationships. CMS agrees that this issue warrants further study and a better developed evidence base before CMS proceeds further with rulemaking.

CMS also notes that many of the areas addressed in the proposed HHA discharge planning requirements were subsequently addressed in a January 13, 2017 final rule titled "Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies" (82 FR 4504), referred to as the "HHA CoP final rule". This rule, for example, required HHAs to communicate with all relevant parties, including physicians who are involved in the patient's HHA plan of care, whenever there are revisions to the plan for patient discharge (§484.60(c)(3)(iii). CMS believes that a separate discharge planning process is unnecessary, and withdraws the majority of general discharge planning requirements it proposed in §484.58(a), with the exception of the IMPACT Act requirements set forth in proposed paragraph (a)(6).

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

CMS finalizes, with modifications, its proposal at §484.58(b) regarding the discharge or transfer summary content. It is finalizing §484.58(b) with the following modifications:

- Revising §484.58(b)(1) to require that, instead of a specified list as proposed, 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.

In the proposed rule, CMS proposed to establish a new standard to require that the HHA send necessary medical information to the receiving facility or health care practitioner, including at the minimum, the same elements as specified for hospitals: demographic information; contact information for the physician responsible for the home health plan of care; advance directive, if applicable; course of illness/treatment; procedures; diagnoses; laboratory results; reconciliation of all discharge medications, etc; and any other information necessary to ensure a safe and effective transition of care that supports the post-discharge goals for the patient. \

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. CMS notes in response that the disparate nature of the comments leads it to conclude that 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 nor a well-develop evidence based to identify best practices in the transfer of information from an HHA to another health care provider. Thus, CMS does not finalize a list of requirements related to the discharge summary.

Instead, CMS finalizes a broader, but flexible requirement described above under which 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. In addition, CMS finalizes that 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. CMS believes that this change will assure that facilities and practitioners have access to the information, as needed, while not overburdening HHAs to preemptively provide such a large volume of information that may not be helpful.

G. Critical Access Hospital Discharge Planning

CMS notes that there is no CAH discharge planning CoP in existing regulations. Current §485.631(c)(2)(ii) requires a CAH to arrange for, or refer patients to, needed services that cannot be furnished at the CAH. In addition, CAHs must ensure that adequate patient health records are maintained and transferred as required when patients are referred. The CoPs at §485.635 require a CAH to develop and keep current a nursing care plan for each patient receiving inpatient services.

CMS proposed to develop discharge planning requirements in the form of five standards at §485.642 and one additional standard at §485.635. Under its proposal, among others, it would require that all inpatients and certain categories of outpatients be evaluated for their discharge needs and the CAH develop a discharge plan. In addition, CMS proposed to require that the

CAH provide specific discharge instructions, as appropriate, for all patients. These provisions and their resolution are discussed in detail below.

With respect to the introductory language of this provision at §485.642, CMS received no substantive comments, and is finalizing with only minor stylistic amendments that it states does not affect the substance of this rule. It now reads, as follows:

> *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.*

1. Design (Proposed §485.642(a))

CMS did not finalize its proposal at §485.642(a) to establish a new standard, "Design," to require a CAH to have policies and procedures to be developed with input from the CAH's professional healthcare staff, nursing leadership as well as other relevant departments; be reviewed and approved by the governing body or responsible individual; and be specified in writing.

CMS states that although it did not receive any comments on this standard, it decided upon further reflection that this requirement may be too process oriented and too prescriptive as written and that further revision to this requirement for CAHs is warranted.

2. Applicability (Proposed §485.642(b))

CMS did not finalize the requirements at proposed §485.642(b), but instead finalizes requirements at §485.642(a) introductory text and §485.642(a)(2), that are scaled back in scope and more flexible that its proposal. Specifically, CMS finalizes the following provisions:

- §485.642(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.

- §485.642(a)(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.

Many commenters had expressed concern over the undue burden that they believe would result from applying a discharge planning process to all patients, as proposed, and maintained that the current evaluation requirement is effective for screening and targeting high-risk patients who have true discharge needs.[4] CMS, in response, agreed that the requirement needs to be scaled back in its scope and applicability and modified into a more flexible requirement.

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

With respect to the discharge planning process for CAHs, CMS finalizes §485.642(c) and redesignates it into §485.642(a) with the following modifications:

- Revises and redesignates §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.

- Revises and redesignates §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.

The finalized provision does not include the ten requirements specified in the proposed rule that CAHs would have had to consider in evaluating patient's discharge, including, but not limited to consideration of admitting diagnosis or reason for registration, readmission risk, relevant psychosocial history, and communication needs, among others.

Several commenters expressed concern that the rural location and small size of CAHs pose difficulties for them in ensuring they have the appropriate staff to implement the proposed discharge planning requirements. In particular, commenters expressed concern that it would present significant burden to CAHs if all patients were required to have discharge planning within 24 hours of admission or registration. In response, CMS modifies its proposals to eliminate the 24 hour proposal and the detailed list of ten requirements CAHs must examine,

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

CMS did not finalize the discharge requirements at §485.642(d), as proposed. Instead, CMS is redesignating the proposed requirement in §485.642(d)(3) as §485.642(b) and eliminating the specific timeframe requirements. Section 485.642(b) as finalized 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,

[4] As initially proposed, the discharge planning process would apply to: (1) all inpatients; (2) outpatients receiving observation services; (3) outpatients undergoing surgery or other same day procedures for which anesthesia or moderate sedation are used; (4) emergency department patients identified in accordance with the CAH's discharge planning policies and procedures by the emergency department practitioner responsible for the care of the patient as needing a discharge plan; and (5) any other category of outpatients as recommended by the medical staff and specified in the CAH's discharge planning policies and procedures approved by the governing body or responsible individual

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.

CMS refers reader to the discussion of comments in the hospital section, which had almost identical provisions. See II.E of this summary.

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

CMS finalizes provisions on CAH transfer of patients to another health care facility it proposed at §485.642(e), with modifications. CMS is revising and redesignating §485.642 as follows:

- Removing proposed §485.642(a) and (b), replacing these standards with revisions, and redesignating them 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 .

The final requirements for the discharge planning process for CAHs for discharging a patient to another health care facility are almost identical to those for hospitals. Comments on these issues are discussed in the hospital section at section II.E of this summary.

III. Regulatory Impact Analysis

A. Overall Economic Impact Estimates

CMS estimates that this final rule meets the threshold as "economically significant" ($100 million or more in any one year), and therefore a regulatory impact analysis was conducted. The budgetary impact of these reforms for which CMS estimates will have a measurable economic effect is summarized in Table 1, duplicated below. This table incorporates both the costs of complying with information collection requirements (ICRs) as well as those costs attributed to the regulatory impact analysis (RIA).

This final rule has estimated total first year costs of $262 million and annual costs thereafter of $215 million.

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

For its estimates on the potential impacts of this final rule, CMS uses 4,900 hospitals, 1,353 CAHs, and 12,600 HHAs that are certified by Medicare and/or Medicaid. The discussion below provides additional detail on the assumptions CMS used to derive the one-time and recurring costs for these entities associated with the discharge planning process and requests for information.

1. Annual (Recurring) Costs

Overall, CMS estimates that that compliance with the new CoP requirements at §484.58 will cost HHAs about $215 million annually broken down as follows:

- An annual cost of $213.4 million for all HHAs to comply with the discharge or transfer summary requirements. CMS assumes that an HHA developing a discharge or transfer summary will require about 10 minutes (0.167 hours) per patient. Thus, for the 12,600 HHAs, CMS estimates that complying with this requirement will require over 3 million burden hours (18 million patients *0.167 hours) at an estimated cost of $213.4 million (3,006,000 x $71 average hourly salary for a RN).

- An annual cost of $1.5 million for all HHAs to comply with additional requests for information made by the facility or health care practitioner. CMS estimates that it will take 15 minutes to process each request and either print and fax, or otherwise send the

additional requested information. This results in a total of 45,000 hours per year (180,000 requests x 0.25 hours per request) at a cost of $1,485,000 (45,000 hours x $33 general office clerk hourly rate). It assumes that providing such documentation will represent an additional burden for those 10 percent of HHAs who are not already engaging in such information sharing practices (i.e., assumes that 90 percent of HHAs already provide such information as standard practice).

2. One-time costs

CMS assumes that hospitals, CAHs, and HHAs will incur one-time costs to review their current policies and procedures and update them so that they can comply with the modified requirements. It estimates $17.7 million for hospitals, $1.9 million for CAHs, and $10.8 million for HHAs. This assumes that compliance will require at least 8 hours of an administrator's time in each setting, along with physician and lawyer time in hospitals, and RN time for hospitals and CAHs. In addition, CMS assumes that the estimated cost to review the rule in order to understand what it requires and what changes the entity will have to make will require $856 per entity (4 hours each x 2 staff x $107 per hour each) for a total cost of $16.1 million ($856 x 18.853 entities).

B. Analysis of Comments

Many commenters expressed concern that CMS underestimated the implementation cost for the proposed requirements for hospitals and, particularly, CAHs. They believed that many of the requirements were burdensome, overly prescriptive and CMS had underestimated the cost of hiring new staff, training existing staff, and updating and changing EHRs. Commenters also disagreed with CMS' estimates on the amount of time that it would take an HHA to develop a discharge plan per patient. One commenter suggested that it would take 10 to 15 minutes and not the 5 minutes CMS assumes. In response, CMS states that it has significantly scaled back its proposed requirements and is finalizing a more limited set of discharge planning and other requirements. It also agrees with commenters that 5 minutes was insufficient and not realistic and chose 10 minutes for the final rule. CMS also notes that the changes it made in the final rule to remove overly prescriptive and costly process requirements have resulted in a reduction of costs by more than one-half.