

Supporting Statement
Medicare and Medicaid Programs:
Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals,
and Home Health Agencies.

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of the collection of information requirements for the proposed rule that would revise the discharge planning requirements that Hospitals, including Long-Term Care Hospitals and Inpatient Rehabilitation Facilities, Critical Access Hospitals, and Home Health Agencies must meet in order to participate in the Medicare and Medicaid programs. The proposed rule would also implement the discharge planning requirements of the Improving Medicare Post-Acute Care Transformation Act of 2014.

Although the current hospital discharge planning process meets the needs of many inpatients released from the acute care setting, some discharges result in less-than-optimal outcomes for patients including complications and adverse events that lead to hospital readmissions. Reducing avoidable hospital readmissions and patient complications presents an opportunity for improving the quality and safety of patient care while lowering health care costs.

The discharge planning process should ensure that patients and, when applicable, their caregivers, are properly prepared to be active partners and advocates for their healthcare and community support needs upon discharge from the hospital or PAC setting. For patients who require PAC services, the discharge planning process should ensure that the transition from one care setting to another (for example, from a hospital to a skilled nursing facility or to home with help from a home health agency or community-based services provider (or both) is seamless. The receiving PAC facilities or organizations should have the necessary information and be prepared to assume responsibility for the care of the patient. When patients or receiving facilities or organizations do not have key information such as the information previously mentioned, they are less able to implement the appropriate post-discharge treatment plans. This puts patients at risk for serious complications and increases their chances of being re-hospitalized.

Therefore, the proposed requirements applicable to the ICRs are as follows: one-time review and revision of current discharge planning requirements for hospitals, HHAs, and CAHs to ensure compliance with the proposed requirements; ongoing compliance with the discharge planning requirements for HHAs and CAHs contained in the proposed rule; inclusion of new categories of patients (e.g., outpatients) in the hospital discharge planning process; and involvement of the practitioner responsible for the care of the patient in the ongoing process of establishing the patient's goals of care and treatment preferences that inform the hospital discharge plan.

This proposed rule would also implement the discharge planning requirements mandated in

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

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

B. Justification

1. Need and Legal Basis

The information collection requirements for which we are requesting OMB approval are listed below. These requirements are among other requirements which are based on criteria prescribed in law and are standards designed to ensure that each hospital, CAH, and HHA safely and effectively delivers care to all residents. The information collections requirements described herein are needed to implement these health and safety standards requirements for all Medicare- and Medicaid-participating hospitals, CAHs, and HHAs. We believe many of the requirements applied to these hospitals, CAHs, and HHAs would impose no burden since a prudent institution would self-impose them in the course of doing business.

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

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1899B in the discharge planning process.

This proposed rule would implement the discharge planning requirements mandated in section 1899B(i) of the IMPACT Act by modifying the discharge planning or discharge summary CoPs for hospitals, CAHs, IRFs, LTCHs, and HHAs. The IMPACT Act identifies LTCHs and IRFs as PAC providers, but the hospital CoPs also apply to LTCHs and IRFs since these facilities, along with short-term acute care hospital, are classifications of hospitals. All classifications of hospitals are subject to the same hospital CoPs. considered short-term acute care hospitals. Therefore, these PAC providers (including freestanding LTCHs and IRFs) are also subject to the proposed revisions to the hospital CoPs.

2. Information Users

The primary uses of this information will be by State agency surveyors, CMS, and the hospitals, CAHs, and HHAs for the purposes of ensuring compliance with Medicare and Medicaid requirements as well as ensuring the quality of care provide to hospital, CAH, and HHA patients.

3. Use of Information Technology

Hospitals, CAHs, and HHAs may use health information technologies (HIT) to store and manage records, consistent with statutory and regulatory requirements for record keeping and confidentiality. Use of certified HIT technology is encouraged but not required, as some facilities, particularly small or rural facilities, may not have electronic capacity at this time. Facilities are free to take advantage of any technologic advances they find appropriate for their needs.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

This information collection does affect small businesses. However, the requirements are sufficiently flexible for facilities to meet them in a way consistent with their existing operations.

6. Less Frequent Collection

CMS does not collect this information directly from hospitals, HHAs, and CAHs on a scheduled basis. Facilities are expected to collect and maintain their own records in a timely fashion and to be able to provide necessary records to State or Federal surveyors when needed to demonstrate compliance with the long term care requirements for participation. With less frequent collection, CMS would not be able to assess or ensure compliance with

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the requirements.

7. Special Circumstances

There are no special circumstances for collecting this information.

8. Federal Register/Outside Consultation

This information collection request is associated with Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies (0938-AS-59), which is scheduled to publish on October 30, 2015.

9. Payments/Gifts to Respondents

There are no payment or gifts to respondents.

10. Confidentiality

We do not pledge confidentiality of aggregate data. We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

The assumptions and estimates used to develop burden estimates are provided in the table below.

Assumptions and Estimates Used Throughout

Number of Medicare, Medicaid, or dually certified Hospitals	4,900*
Number of Medicare, Medicaid, or dually certified HHAs	11,930*
Number of Medicare, Medicaid, or dually certified CAHs	1,328*
Hourly wage of RN	\$67.00**
Hourly wage of Hospital CEO/Administrator	\$174.00**
Hourly wage of HHA or CAH CEO/Administrator	\$98.00**
Hourly wage of Advanced Practice Registered Nurse	\$94.00**
Hourly wage of Physician Assistant	\$94.00**
Hourly wage of Healthcare Social Worker	\$52.00**
Hourly wage of Clerical Worker	\$32.00**

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Hourly wage of Physician	\$187.00**
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*Number of facilities is based on Medicare's Certification and Survey Provider Enhanced Reporting (CASPER) as of April 1, 2015.

**Hourly wage estimates are based on the Bureau of Labor Statistics Occupational Outlook Handbook, 2014-2015 edition, and include a 100 percent benefits and overhead package.

A. Hospital Discharge Planning (§482.43)

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

It should be noted here that the proposed requirements at §482.43(c)(8) and §482.43(c)(9) (and all similar proposed requirements set out at proposed §485.642(c)(8) and (9) for CAHs and §484.58(a)(6) and (7) for HHAs), which correspond to the requirements of the IMPACT Act, are exempted from the application of the PRA pursuant to section 1899B(m). Therefore, we are not required to estimate the public reporting burden for information collection requirements for these specific elements of the proposed rule in accordance with chapter 35 of title 44, United States Code. Nor are we required to undergo the specific public notice requirements of the PRA. Therefore, the estimates we provide in the Regulatory Impact Analysis (RIA) section of this proposed rule are essentially identical to those we would estimate under the PRA with respect to the elements set out in section 1899B of the Act. The public comment period on the proposed rule will give those affected an equivalent opportunity with the greater procedural benefits of the Administrative Procedure Act and Executive Order 12866. The exemption created by the IMPACT Act does not exempt the entirety of this proposed rule from PRA analysis. We further note that these proposed rules deal with the transmission of data on quality measures and data on resource use measures to patients that, are provided by the government to health care providers, not with the costs associated with its preparation. This rule does not deal with those costs.

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

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patients (§482.43(c)(6)). Thus, hospitals are already providing counseling to patients, their families, or other interested parties and are providing certain written information.

Whenever a patient is discharged or transferred to another facility, proposed §482.43(e) would require hospitals to send necessary medical information to the receiving facility at the time of transfer. The necessary information that the hospital must send to the receiving facility includes all the items listed at proposed §482.43(e)(2)(i) through (viii). The current hospital CoPs already require hospitals to send along with any patient that is transferred or referred to another facility the necessary medical information for the patient's follow-up or ancillary care to the appropriate facility (§482.43(d)). Overall, we believe that almost all of the proposed changes for hospitals constitute a clarification and restatement of the current requirements along with their interpretive guidelines, or simply state as requirements practices that most hospitals already follow for most patients. For example, we believe that medication reconciliation is a near universal practice for inpatients. Thus, we believe that hospitals are already following most of these proposed requirements and therefore we will not be assessing any additional burden for this section beyond our estimates of the one-time cost to hospitals to modify their policies and procedures in order to ensure that they are meeting the requirements of this proposed rule. There are, however, some proposed requirements that expand beyond current practice, or that fewer hospitals currently follow. These proposed requirements included:

- Discharge plans for certain categories of outpatients, including, but not limited to patients receiving observation services, patients who are undergoing surgery or other same-day procedures where anesthesia or moderate sedation is used, emergency department patients who have been identified by a practitioner as needing a discharge plan, and any other category of outpatient as recommended by the medical staff, approved by the governing body and specified in the hospital's discharge planning policies and procedures; and
- The practitioner responsible for the care of the patient must be involved in the ongoing process of establishing the patient's goals of care and treatment preferences that inform the discharge plan, just as they are with other aspects of patient care during the hospitalization or outpatient visit.

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

With respect to the one-time costs of reviewing the newly stated requirements and of reviewing and in some cases modifying existing procedures to come into compliance, we estimate that this would require a physician, a registered nurse, and an administrator using the average hourly salaries as estimated in this proposed rule. We estimate that each person would spend 8 hours on this activity for a total of 24 hours per hospital at a cost of \$3,424 ((8 hours x \$67 for a registered nurse's hourly salary) + (8 hours x \$174 for hospital CEO/administrator's hourly salary) + (8 hours x \$187 for a physician's hourly salary)). The total burden hours are

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117,600 (24 hours x 4,900 hospitals). For all hospitals to comply with this requirement, we estimate a total one-time cost of approximately \$17 million (4,900 hospitals x \$3,424). These time estimates are based on our best estimates of the time needed, on average, to review the final rule, compare its provisions with current practice at the hospital, and determine what changes would be needed and what instructions would need to be issued. For some hospitals, less time would be needed, and for some hospitals more, depending on current practices. These estimates are based on the judgments of CMS staff involved in the Survey and Certification process. We are unaware of any “time and motion” or similar studies that would provide a quantitative and reliable source for such estimates. We welcome comments and data that would help us improve the estimates.

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

For the estimated cost of hospitals to provide additional discharge plans for the proposed new categories of outpatients, we started with the most recent data from the CDC on hospital outpatient and emergency department (ED) visits that showed approximately 126 million visits and 118 million visits (not including the 18.3 million emergency department visits that resulted in inpatient admissions), respectively, in 2011 (<http://www.cdc.gov/nchs/fastats/hospital.htm>). We believe that only 5 percent of hospital outpatient visits, or approximately 6 million visits, and 5 percent of ED visits, or approximately 6 million visits, would need a discharge plan. We base this belief on our experience with hospitals that shows that most outpatient visits, similar to a physician’s office visit, do not need a discharge plan of any type and that most ED visits already receive some type of discharge plan.

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

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

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

We believe that hospital APRNs and PAs would spend equal time as physicians, RNs, and healthcare social workers on discharge planning (5 minutes or 0.083 hours) on an equal

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

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

B. Home Health Discharge Planning (§484.58)

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

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

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

We propose to require that the evaluation of the patient’s discharge needs and discharge plan must be documented, completed on a timely basis and be based on the patient’s needs to ensure that the patient’s discharge or transfer is not unduly delayed. We believe that HHAs would establish more specific time frames for completing the evaluation and discharge plans based on the needs of their patients and their own operations. We propose to require that the evaluation be included in the medical record. We propose that the results of the evaluation be discussed with the patient or patient’s representative. Furthermore, all relevant patient information available to or generated by the HHA itself must be incorporated into the discharge plan to facilitate its implementation and to avoid unnecessary delays in the patient’s discharge or transfer.

We base our HHA burden cost estimates on those discussed previously in this proposed rule for hospitals and CAHs with the relevant modifications for HHAs. First, HHAs would need to review their current policies and procedures and update them so that they comply with the

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requirements in proposed §484.58(a). This would be a one-time burden on the HHA. We estimate that this would require a physician, a registered nurse, and an administrator using the average hourly salaries as estimated in this proposed rule. Note that we are estimating a lower average hourly salary for an HHA administrator than that previously estimated for a hospital CEO/administrator. We estimate that each person would spend 8 hours on this activity for a total of 24 hours per HHA at a cost of \$2,816 ((8 hours x \$67 for a RN's hourly salary) + (8 hours x \$98 for an administrator's hourly salary) + (8 hours x \$187 for a physician's hourly salary)). For all HHAs to comply with this requirement, we estimate a total one-time cost of approximately \$34 million (11,930 HHAs x \$2,816).

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

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

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

We propose to include these elements in the discharge plan to provide the clear and comprehensive summary that is necessary for effective and efficient follow-up care planning and

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implementation as the patient transitions from HHA services to another appropriate health care setting.

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

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

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

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

C. Critical Access Hospital Discharge Planning (§485.642)

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

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

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

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

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

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

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

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

The burden associated with the requirement that a practitioner responsible for the patient's care be involved with the patient's discharge would include the time needed for a practitioner to assist in establishing the discharge plan. We believe that practitioner involvement in the establishing of the discharge plan would constitute a usual and customary business practice as defined in the implementing regulations of the PRA at 5 CFR 320.3(b)(2) and that CAHs are already doing this. The majority of CAHs that are deemed for participation in Medicare are accredited by The Joint Commission, which requires a CAH to have "the patient, the patient's family, *licensed independent practitioners, physicians, clinical psychologists, and staff involved in the patient's care, treatment, and services* [emphasis added] participate in

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planning the patient's discharge or transfer." Such practitioner involvement (where indicated and where feasible) is in our view an essential part of patient care and one that we expect CAH staff carefully follow wherever possible. Therefore, we will not be assessing any burden for this activity.

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

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

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

The burden from the requirement to include discharge instructions in the discharge plan and document those instructions is the resources needed to develop the discharge plan and instructions. Based on our experience with the 1,328 CAHs, we believe they are already doing some form of discharge planning and providing discharge instructions for most of their patients. However, we do not believe they are providing this care for all of their patients. Of the approximately 600,000 patients discharged from CAHs each year, we estimate that about 60,000 additional patients would require discharge planning to comply with the requirement in this section. A nurse would probably perform this activity at an hourly salary of \$67. This activity should require 30 minutes or 0.5 hours. Thus, for the 1,328 CAHs, we estimate that complying with this requirement would require 30,000 burden hours (60,000 patients x 0.5 hours) at a cost of \$2 million (30,000 x \$67 hourly nurse's salary). Approximately 5 minutes of this time would

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be spent consulting with either the MD/DO or the APRN/PA at a cost of \$702,180 (60,000 patients x 0.083 hours x \$141(((\$187 + \$94)/2)), resulting in an approximate total of \$2.7 million annually.

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

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

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

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

Table 1 below summarizes the estimated annual reporting and recordkeeping burdens for this proposed rule.

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TABLE 1—ESTIMATED ANNUAL REPORTING AND RECORDKEEPING BURDENS

Regulation Section(s)	OMB Control No.	Number Of Respondents	Number Of Responses	Burden Per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting (\$)	Total Cost (\$)
§482.43(a)	0938-XXXX	4,900	4,900	8	39,200	67	2,626,400
§482.43(a)	0938-XXXX	4,900	4,900	8	39,200	174	6,820,800
§482.43(a)	0938-XXXX	4,900	4,900	8	39,200	187	7,330,400
§482.43(b)	0938-XXXX	4,900	13,000,000	0.083	1,079,000	99	106,821,000
§484.58(a)	0938-XXXX	11,930	11,930	8	95,440	67	6,394,480
§484.58(a)	0938-XXXX	11,930	11,930	8	95,440	98	9,353,120
§484.58(a)	0938-XXXX	11,930	11,930	8	95,440	187	17,847,280
§§484.58(a) & (b)	0938-XXXX	11,930	18,000,000	0.033	594,000	187	111,078,000
§§484.58(a) & (b)	0938-XXXX	11,930	18,000,000	0.05	900,000	52	46,800,000
§§484.58(a) & (b)	0938-XXXX	11,930	18,000,000	0.083	1,494,000	67	100,098,000
§§484.58(a) & (b)	0938-XXXX	11,930	18,000,000	0.042	756,000	32	24,192,000
§485.642(b)	0938-XXXX	1,328	1,328	16	21,248	67	1,423,616
§485.642(b)	0938-XXXX	1,328	1,328	16	21,248	187	3,973,376

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§485.642(b))	0938-XXXX	1,328	1,328	16	21,248	98	2,082,304
§485.642(c))	0938-XXXX	1,328	120,000	0.083	9,960	94	936,240
§485.642(c))	0938-XXXX	1,328	30,000	0.033	990	187	185,130
§485.642(d))	0938-XXXX	1,328	60,000	0.5	30,000	67	2,010,000
§485.642(d))	0938-XXXX	1,328	60,000	0.083	4,980	141	702,180
§485.642(e))	0938-XXXX	1,328	600,000	0.05	30,000	67	2,010,000
Total		18,158	85,924,474		5,366,594		453,520,660

Total burden hours requested equals 5,366,594 hours.

13. Capital Costs

There are no capital/maintenance costs associated with the information collection requirements contained in this rule.

14. Cost to Federal Government

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

15. Changes to Burden

This is a new information collection requirement.

16. Publication/Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS has no objections to displaying the expiration date for this information collection request. We are requesting a three-year approval, the maximum allowed under the PRA. Please note that this information collection request does not utilize information collection instruments; however, should CMS develop any supplemental instructions or guidance documents, the documents will contain the OMB control number and the expiration date.