administration calendar day is for the day on which home infusion therapy services are furnished by skilled professional(s) in the individual's home on the day of infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. An infusion drug administration visit that begins in one calendar day and spans into the next calendar day would be considered one visit using the date the visit ended as the service date. We are soliciting comment on the proposed definition of infusion drug administration calendar day in regulation, as detailed in section IX of this proposed rule.

c. Eligible Home Infusion Suppliers, Eligible Individuals, and Relationship to Home Health

Section 1842(u)(7)(F) of the Act defines eligible home infusion suppliers as suppliers that are enrolled in Medicare as pharmacies that provide external infusion pumps and external infusion pump supplies, and that maintain all pharmacy licensure requirements in the State in which the applicable infusion drugs are administered. This means that existing DME suppliers that are enrolled as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers, as are potential pharmacy suppliers that enroll and comply with the Medicare program's supplier standards (found at 42 CFR 424.57(c)) and quality standards to become accredited for furnishing external infusion pumps and supplies. 97 Home infusion therapy services are furnished by eligible home infusion suppliers in the individual's home to an individual who is under the care of an applicable provider and where there is a plan of care established and periodically reviewed by a physician prescribing the type, amount, and duration of infusion therapy services. In section VI.C.2.f below, regarding the home infusion therapy benefit for CY 2021 and subsequent years, we are soliciting comments

97 https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/DMEPOSQuality/DMEPOSQualBooklet-905709.html

regarding the interaction between home infusion therapy services and home health services. However, for purposes of this proposed temporary transitional payment for home infusion therapy services for CYs 2019 and 2020, we anticipate the relationship between home infusion therapy and home health to be as described in section VI.C.2.f of this proposed rule.

d. Payment Categories

As outlined in section 1834(u)(7)(C) of the Act, identified HCPCS codes for transitional home infusion drugs are assigned to three payment categories for which a single payment amount will be established for home infusion therapy services furnished on each infusion drug administration calendar day. Payment category 1 includes antifungals and antivirals, uninterrupted long-term infusions, pain management, inotropic, and chelation drugs. Payment category 2 includes subcutaneous immunotherapy infusions. Payment category 3 includes certain chemotherapy drugs. Table 55 provides the complete list of J-codes associated with the infusion drugs that fall within each of the payment categories.

TABLE 55: INFUSION DRUG J-CODES ASSOCIATED WITH TEMPORARY TRANSITIONAL PAYMENT CATEGORIES FOR HOME INFUSION THERAPY SERVICES

J-Code	Drug
Category 1	
J0133	Injection, acyclovir, 5 mg
J0285	Injection, amphotericin b, 50 mg
J0287	Injection, amphotericin b lipid complex, 10 mg
J0288	Injection, amphotericin b cholesteryl sulfate complex, 10 mg
J0289	Injection, amphotericin b liposome, 10 mg
J0895	Injection, deferoxamine mesylate, 500 mg
J1170	Injection, hydromorphone, up to 4 mg
J1250	Injection, dobutamine hydrochloride, per 250 mg
J1265	Injection, dopamine hcl, 40 mg
J1325	Injection, epoprostenol, 0.5 mg
J1455	Injection, foscarnet sodium, per 1000 mg
J1457	Injection, gallium nitrate, 1 mg
J1570	Injection, ganciclovir sodium, 500 mg
J2175	Injection, meperidine hydrochloride, per 100 mg
J2260	Injection, milrinone lactate, 5 mg
J2270	Injection, morphine sulfate, up to 10 mg
J2274	Injection, morphine sulfate, preservative-free for epidural or intrathecal use, 10 mg

J2278	Injection, ziconotide, 1 microgram
J3010	Injection, fentanyl citrate, 0.1 mg
J3285	Injection, treprostinil, 1 mg
Category 2	
J1555 JB98	Injection, immune globulin (cuvitru), 100 mg
J1559 JB	Injection, immune globulin (hizentra), 100 mg
J1561 JB	Injection, immune globulin, (gamunex-c/gammaked), non-lyophilized (e.g., liquid), 500 mg
J1562 JB	Injection, immune globulin (vivaglobin), 100 mg
J1569 JB	Injection, immune globulin, (gammagard liquid), non-lyophilized, (e.g., liquid), 500 mg
J1575 JB	Injection, immune globulin/hyaluronidase, (hyqvia), 100 mg immune globulin
Category 3	
J9000	Injection, doxorubicin hydrochloride, 10 mg
J9039	Injection, blinatumomab, 1 microgram
J9040	Injection, bleomycin sulfate, 15 units
J9065	Injection, cladribine, per 1 mg
J9100	Injection, cytarabine, 100 mg
J9190	Injection, fluorouracil, 500 mg
J9200	Injection, floxuridine, 500 mg
J9360	Injection, vinblastine sulfate, 1 mg
J9370	Injection, vincristine sulfate, 1 mg

The payment category for subsequent transitional home infusion drug additions to the LCDs and compounded infusion drugs not otherwise classified, as identified by HCPCS codes J7799 and J7999, will be determined by the Medicare administrative contractors.

e. Payment Amounts

As set out at new section 1834(u)(7)(D) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L. 115-123), each payment category will be paid at amounts in accordance with the Physician Fee Schedule for each infusion drug administration calendar day in the individual's home for drugs assigned to such category without geographic adjustment. Table 56 provides the payment categories associated with the HCPCS codes.

TABLE 56: PAYMENT CATEGORIES FOR TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES

HCPCS CODE	DESCRIPTION	UNITS

98 The JB modifier indicates that the route of administration is subcutaneous.

CATEGORY 1		
96365	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration)- up to one hour	1
96366	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration) - each additional hour	3
CATEGORY 2		
96369	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration) – up to one hour	1
96370	Therapeutic, Prophylactic, and Diagnostic Injections and Infusions (Excludes Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration) - each additional hour	3
CATEGORY 3		
96413	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- up to one hour	1
96415	Injection and Intravenous Infusion Chemotherapy and Other Highly Complex Drug or Highly Complex Biologic Agent Administration- each additional hour	3

Section 1834(u)(7)(E)(ii) of the Act requires that in the case that two (or more) home infusion drugs or biologicals from two different payment categories are administered to an individual concurrently on a single infusion drug administration calendar day, one payment for the highest payment category would be made.

f. Billing

For eligible home infusion suppliers to bill for home infusion therapy services for an infusion drug administration calendar day, we will create three new HCPCS G-codes for each of the three payment categories. The eligible home infusion supplier would submit, in line-item

detail on the claim, a G-code for every visit made by the nurse to provide professional services to the patient in his/her home on a day in which a drug is being infused. Each visit reported would include the length of time in which professional services were provided (in 15 minute increments). However, only one payment would be made per infusion drug administration calendar day at the standard amount described by each of the payment categories noted previously, for a total payment equivalent to 4 hours per infusion drug administration calendar day. These G-codes could be billed separately from or on the same claim as the DME, supplies, and infusion drug; and would be processed through the DME MACs. The supplier furnishing the DME, pump, the infusion drug, and other supplies must also provide the professional services under the home infusion therapy benefit during the temporary transitional payment period.

For the purposes of this temporary transitional payment for home infusion therapy services, section 1834(u)(7)(D)(i) requires that payment amounts would be equal to the amounts determined under the Physician Fee Schedule established under section 1848 of the Act for services furnished during the year for codes and units for such codes specified without application of geographic wage adjustment under section 1848(e) of the Act. In the event that multiple drugs, which are not all assigned to the same payment category, are administered on the same infusion drug administration calendar day, section 1834(u)(7)(E)(ii) requires that a single payment would be made that is equal to the highest payment category. In order to implement the requirements of section 1834(u)(7) of the Act for this temporary transitional payment, we would issue a Change Request (CR) prior to implementation of this temporary transitional payment, including the G-codes needed for billing, outlining the requirements for the claims processing changes needed to implement this payment.

2. Solicitation of Public Comments Regarding Payment for Home Infusion Therapy Services for CY 2021 and Subsequent Years

Upon the expiration of the home infusion therapy services temporary transitional payment, we would be fully implementing the home infusion therapy services payment system under section 1834(u)(1) of the Act, as added by section 5012 of the 21st Century Cures Act (Pub. L. 114-255). In anticipation of future rulemaking, we are soliciting comments regarding the payment system for home infusion therapy services beginning in CY 2021.

a. Relationship to DME

As mentioned previously, Medicare Part B covers certain infusion pumps and supplies (including certain home infusion drugs) that are necessary for the effective use of the infusion pump, through the DME benefit. To be covered under the Part B DME benefit, the drug must be reasonable and necessary for the treatment of illness or injury or to improve the function of a malformed body member, and the drug must be necessary for the effective use of the DME. However, there is no separate Medicare Part B DME payment for professional services associated with the administration of home infusion drugs, including nursing services, or for training and education, monitoring, and remote monitoring services. Therefore, we consider the home infusion therapy benefit principally to be a separate payment in addition to the existing payment made under the DME benefit, thus explicitly and separately paying for the home infusion therapy services.

b. Definition of Infusion Drug Administration Calendar Day

Section 1834(u)(7)(E)(i) of the Act applies the same definition of "infusion drug administration calendar day" for both the home infusion therapy temporary transitional payment and the home infusion therapy services benefit. We anticipate retaining the definition

of infusion drug administration calendar day, as proposed in section IV.C.2. of this proposed rule for the full implementation of the home infusion therapy services benefit. This means that payment for an infusion drug administration calendar day is for the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of infusion drug administration. An infusion drug administration visit that begins in one calendar day and spans into the next calendar day would be considered one visit using the date the visit ended as the service date. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel. We are soliciting comments on the definition as discussed in section IV.C.2. of this proposed rule.

c. Payment Basis, Limitation on Payment, Required and Discretionary Adjustments, and Billing Procedures

Section 1834(u)(1)(A) of the Act requires the establishment of a unit of single payment for each infusion drug administration calendar day. Section 1834(u)(1)(A)(iii) of the Act limits the unit of single payment by requiring that it must not exceed the amount determined under the fee schedule under section 1848 of the Act for infusion therapy services furnished in a calendar day if furnished in a physician's office, and the single payment must not reflect more than five hours for a particular therapy in a calendar day. Additionally, section 1834(u)(1) of the Act includes provisions for payment adjustments to the unit of single payment for home infusion therapy. Section 1834(u)(1)(B) of the Act requires adjustments to reflect factors such as patient acuity and complexity of drug administration, and a geographic wage index and other costs that may vary by region. While the three payment categories used for the temporary transitional payment in CYs 2019 and 2020 reflect the therapy type and complexity of the drug

administration under the Physician Fee Schedule, we are soliciting comments on other ways to account for therapy type and complexity of administration, as well as ways to capture patient acuity.

Section 1834(u)(1)(B)(i) of the Act requires that the single payment amount be adjusted by a geographic wage index; therefore, we are considering using the Geographic Practice Cost Indices (GPCIs) to account for regional variations in wages and adjust the payment for the professional services. A GPCI has been established for every Medicare payment locality for each of the three components of a procedure's relative value unit (RVU) (for example, the RVUs for work, practice expense, and malpractice). The GPCIs are applied in the calculation of a fee schedule payment amount by multiplying the RVU for each component times the GPCI for that component.[99] Finally, section 1834(u)(1)(C) of the Act allows for discretionary adjustments which may include outlier situations and other factors as deemed appropriate by the Secretary, and are required to be made in a budget neutral manner. We request feedback on situations that may incur an outlier payment and potential designs for an outlier payment calculation.

For CY 2021 and subsequent years, although not required by law, the Part B qualified home infusion therapy supplier could potentially submit a claim for home infusion therapy services on a Part B practitioner claim and processed through the A/B MACs, rather than the DME MACs. We are soliciting comment on whether submitting a Part B practitioner claim processed through the A/B MACs is reasonable given that other types of suppliers and providers of services (such as physicians and HHAs), and not just DME suppliers, can meet the requirements under section 1861(iii) of the Act, such as accreditation, to provide home infusion

99 https://www.cms.gov/apps/physician-fee-schedule/documentation.aspx

therapy services. In addition, when Part B practitioner claims are processed through the A/B MACs a mechanism is already in place for the geographic wage adjustment, as required for the home infusion therapy payment system, and we are considering the use of GPCI as described previously. In order to bill for the home infusion therapy services, beginning on January 1, 2021, a qualified home infusion therapy supplier will need to enroll in Medicare as a Part B Home Infusion Therapy supplier. Additionally, in order to furnish DME equipment and supplies, that same qualified home infusion therapy supplier must also be enrolled as a DME supplier since the home infusion therapy services are required to be for the furnishing of DME infusion drugs through a DME infusion pump. In other words, both enrollments would be necessary for the same supplier to bill for home infusion therapy services and the DME equipment and supplies. Therefore, in order to be paid for all elements of home infusion therapy, two claims would need to be submitted: (1) the first claim for the DME drug, equipment, and supplies on the 837P/CMS-1500 professional and supplier claims form submitted to the DME MAC; and (2) a second claim for the professional services on the 837P/CMS-1500 professional and supplier claims form submitted to the A/B MAC.

We invite comments on the unit of single payment, limitations on payment, and required and discretionary adjustments. We are also soliciting comments on whether it is reasonable to require two separate claims submissions to account for all components of home infusion therapy using the 837P/CMS-1500 professional and supplier claims form, and submitting claims to both the DME MACs and the A/B MACs for processing. Finally, we are soliciting any additional suggestions as to how qualified home infusion therapy suppliers should bill and be paid for services under the home infusion therapy benefit.

d. Definition of Professional/Nursing Services and Monitoring Related to the Administration of

Home Infusion Drugs

In accordance with section 1861(iii)(2) of the Act, items and services covered under the home infusion therapy benefit are as follows:

- Professional services, including nursing services, furnished in accordance with the plan.
- Training and education (not otherwise paid for as DME),
- Remote monitoring, and monitoring services for the provision of home infusion drugs furnished by a qualified home infusion therapy supplier.

Section 1861(n) of the Act defines DME as equipment used in the patient's home. Furthermore, the regulations at 42 CFR 424.57(c)(12) state that the DME supplier "must document that it or another qualified party has at an appropriate time, provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively." As the medications in the DME external infusion pump LCDs are considered supplies to the external infusion pump, and have been identified as drugs and biologicals that can be self-infused in the home, ongoing nursing supervision is not required once the patient and/or caregiver has been sufficiently taught to safely manage the pump. We recognize that the DME supplier standards require a DME supplier to document that it or another qualified party has at an appropriate time provided beneficiaries with necessary information and instructions on how to use Medicare-covered items safely and effectively (42 CFR 424.57(c)(12)). Therefore, the in-home nursing services under the home infusion therapy benefit would include a limited amount of teaching and training on the provision of home infusion drugs that is not already covered under the DME benefit in accordance

In determining the reasonable and necessary number of infusion therapy visits, the home infusion therapy supplier must consider whether the training and education provided constitutes

reinforcement of teaching provided previously in an institutional setting or in the home, or whether it represents initial instruction. Where the teaching represents initial instruction, the supplier should consider patient acuity, including the unique abilities of the patient, and complexity of the infusion. Where the teaching constitutes reinforcement, the supplier should evaluate the patient's retained knowledge and anticipated learning progress to determine the appropriate number of visits. Re-teaching or retraining for an appropriate period may be considered reasonable and necessary where there is a change in the infusion protocol or the patient's condition that requires re-teaching, or where the patient, family, or caregiver is not properly carrying out the task. The medical record should document the anticipated number of training and education visits required, patient/caregiver response to training, and if necessary, the reason that the re-teaching or retraining is required. Where it becomes apparent after a reasonable period of time that the patient/caregiver is not able to be trained, or if the patient/caregiver has been taught to safely and effectively use the infusion pump in the home, then further teaching and training would cease to be reasonable and necessary. In accordance with section 1861(iii)(1)(B), an individual must be under a plan of care established by a physician, prescribing the type, amount, and duration of infusion therapy services that are to be furnished in coordination with the furnishing of home infusion drugs under Part B. These home infusion drugs, defined under section 1861(iii)(3)(C) of the Act, must be administered intravenously, or subcutaneously for an administration period of 15 minutes or more through a pump that is an item of DME in order for home infusion therapy services to be reasonable and necessary for the treatment of the illness or injury. In order to satisfy the definition of DME, an item must be appropriate for use in the home. In this case, in order to be considered appropriate for use in the home, the patient must be able to safely and effectively operate the infusion

pump. Therefore, if a patient is unable to safely and effectively operate the infusion pump in the home, then the patient would not be eligible for the home infusion therapy benefit.

It is important to reiterate that the professional services covered under this benefit are not intended to provide on-going nursing supervision throughout each infusion. If applicable, the reason why a training was unsuccessful should be documented in the record. We invite comments regarding what constitutes a reasonable and necessary amount of training and education for the provision of home infusion drugs. We outline in this section additional, more detailed information on the professional and nursing services that would be covered, as well as remote monitoring services for the provision of home infusion drugs, as defined in 1861(iii)(3)(C) of the Act, relative to the therapy types currently included in the DME external infusion pump LCD 100.

(1) Central Vascular Access Device Maintenance

As many of the drugs and biologicals included in the DME external infusion pump LCD are given continuously, given on a long-term basis, or are vesicants or irritants that should not be given peripherally, many beneficiaries would likely have central vascular access devices (CVAD), such as peripherally inserted central catheters (PICC), central lines, or ports requiring training and education regarding maintenance and hygiene, and site care and dressing changes. The qualified home infusion therapy supplier would be responsible for educating the patient on properly disinfecting access points and connectors, what to do in the event of a dislodgement or occlusion, and signs/symptoms of infection. This also includes teaching the patient about flushing the CVAD after the infusion to ensure all of the medication has been flushed through the tubing and catheter, and locking the catheter to prevent blood from backing into the catheter

100 https://med.noridianmedicare.com/documents/2230703/7218263/External+Infusion+Pumps+LCD

and clotting. Education regarding specific techniques and solutions (saline or heparin) may be given to minimize catheter occlusion.[101]

(2) Medication Education and Disease Management

The qualified home infusion therapy supplier would be responsible for ensuring that the patient has been properly educated about his/her disease, medication therapy, and lifestyle changes. This could include self-monitoring instruction (for example, nutrition, temperature, blood pressure, heart rate, daily weight, abdominal girth measurement, edema, urine output) and identification of complications or problems necessitating a call to the infusion nurse/pharmacist, or emergency protocols if they arise. The qualified home infusion therapy supplier would ensure proper understanding of the medication therapy including: drug; route of administration; prescription (dosage, how often to administer, and duration of therapy); side effects and interactions with other medications; adverse reactions to therapy; goals of therapy; and indications of progress. Lifestyle education regarding behavior and food/fluid modifications/restrictions, symptom management, and infection control are also important aspects of this education. As some drugs covered under the DME benefit involve extensive lifestyle changes and dietary restrictions, training and education as included in the home infusion therapy benefit could entail any ancillary services such as visits with social workers or dieticians as needed, and documented in the medical record. For patients on continuous, potentially life long IV therapy, the nurse, social worker, or dietician would assess the need for further training and education regarding the concept of long-term drug infusion and address aspects of life-style changes and realistic expectations for life with an infusion pump.

(3) Patient Evaluation and Assessment

101 Gabriel J (2013) Venous access devices part 2: preventing and managing complications of CVADs. *Nursing Times*; 109: 40, 20-23.

Comprehensive patient assessment is imperative when providing home infusion therapy in order to ensure the accuracy of the medication administration and safety of the patient, and to determine whether changes in the home infusion therapy plan of care are necessary. The qualified home infusion therapy supplier would evaluate patient history, current physical and mental status, including patient response to therapy, any adverse effects or infusion complications, lab reports, cognitive and psychosocial status, family/care partner support, prescribed treatment, concurrent oral prescriptions, and over-the-counter medications. This includes obtaining any necessary blood-work and vital signs.

(4) Medication Administration

As the DME supplier is responsible, under the DME benefit,102 for training the patient and caregiver on pump operation, maintenance, and troubleshooting; the qualified home infusion therapy supplier would be responsible for all other aspects of medication administration, including inspection of medications, containers, supplies prior to use; proper drug storage and disposal; household precautions for chemotherapy drugs including spills, handling body wastes, and physical contact precautions; hand hygiene and aseptic technique; pre/post medication/hydration administration; and medication preparation.

(5) Remote Monitoring and Monitoring Services

Section 1861(iii)(3)(D)(i)(II) of the Act requires that the qualified home infusion therapy supplier "ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis." Therefore, the qualified home infusion therapy supplier would closely monitor lab values, patient response to therapy, and assess compliance. Direct communication and coordination with the patient, caregivers, applicable

102 https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/downloads/DMEPOSAccreditationStandardsCMB.pdf

providers, and pharmacist regarding changes in the patient's condition should be on-going so that any adjustment to treatment is made as needed and in a timely fashion.

Monitoring services, as indicated on the plan of care, would dictate either the need for daily monitoring of indicated vitals (through remote monitoring) or specify the interval for in-person evaluation and assessment of the patient. The use of remote monitoring services for those patients receiving home infusion therapy would likely be limited to patients receiving continuous infusion medications as identified in the plan of care. These patients are considered high risk patients and require daily monitoring, but generally do not need to be seen by a practitioner daily. This can be achieved, for example, through the use of a remote monitoring service that includes monitoring equipment through which the patient electronically submits self-obtained vital signs, such as weight, blood pressure, and heart rate. In this example, an off-site monitoring service would communicate any abnormal results to the home infusion therapy supplier for analysis and consultation with the provider overseeing the patient's care (that is, physician, nurse practitioner, or physician assistant) regarding potential treatment plan changes.

We invite comments on any additional interpretations of professional, nursing, training and education, and monitoring services that may be considered under the scope of the home infusion therapy benefit. We also specifically welcome comments on the use of remote monitoring under the home infusion therapy benefit.

e. The Role of Prior Authorization Under the Home Infusion Therapy Benefit

Section 1834(u)(4) of the Act states that the Secretary may apply prior authorization for home infusion services. Generally, prior authorization requires that a decision by a health insurer or plan be rendered to confirm that a health care service, treatment plan, prescription

drug or durable medical equipment is medically necessary.103 Prior authorization helps to ensure that a service, such as home infusion therapy, is being provided appropriately. Private health plans generally require prior authorization before home infusion therapy can begin. We would maintain the discretion to decide if certain drugs or frequency in visits require prior authorization before therapy can be covered. The emphasis would be on the appropriateness of the drug and the necessity of associated professional services and not the site of care. We are soliciting comments as to whether and how prior authorization could potentially be utilized for home infusion therapy.

f. Home Infusion Therapy and the Relationship to/Interaction with Home Health

A beneficiary does not have to be considered confined to the home (that is, homebound) in order to be eligible for the home infusion therapy benefit. However, homebound beneficiaries requiring home health services also may be eligible for the home infusion therapy benefit. Therefore, there may be circumstances when a patient may utilize both the home health benefit and the home infusion therapy benefit concurrently.

HHAs are required to furnish necessary DME and coordinate home infusion services when a patient is under a home health plan of care. In accordance with the Home Health Conditions of Participation at 42 CFR 484.60, the HHA must assure communication with all physicians involved in the plan of care, as well as integrate orders and services provided by all physicians and disciplines. In order to qualify for the Medicare home health benefit, the beneficiary must--

- Be confined to the home;
- Be under the care of a physician;
- Receive services under a plan of care established and periodically reviewed by a

103 https://www.healthcare.gov/glossary/preauthorization/

physician;

- Be in need of skilled nursing care on an intermittent basis or physical therapy or speech-language pathology, or have a continuing need for occupational therapy; and
- Have had a face-to-face encounter related to the primary reason for home health care with an allowed provider type and within the required timeframe.

If a patient meets the requirements listed previously and a home health visit is furnished that is unrelated to home infusion therapy, then payment for the home health visit would be covered by the HH PPS payment and billed on the home health claim. When the HHA providing services under the Medicare home health benefit is also the same entity furnishing services as the qualified home infusion therapy supplier, and a home visit is exclusively for the purpose of furnishing items and services related to home infusion therapy, the HHA would submit a claim for payment as a home infusion therapy supplier and receive payment under the home infusion therapy benefit. If the home visit includes the provision of other home health services in addition to, and separate from, items and services related to the home infusion therapy, the HHA would submit both a home health claim and a home infusion therapy claim, but must separate the time spent performing services covered under the HH PPS from the time spent performing services covered under the home infusion therapy benefit. We anticipate this would be similar to the approach for furnishing negative pressure wound therapy using a disposable device as described in the regulations at 42 CFR 484.205(b).

We are soliciting feedback on the relationship between the Medicare home health benefit and the home infusion therapy benefit, including how payment would be made for a beneficiary who meets eligibility requirements for home health services and home infusion therapy services.

VII. Changes to the Accreditation Requirements for Certain Medicare-Certified Providers and Suppliers

A. Background

To participate in the Medicare program, Medicare-certified providers and suppliers of health care services, must be substantially in compliance with specified statutory requirements of the Act, as well as any additional regulatory requirements related to the health and safety of patients specified by the Secretary of the Department of Health and Human Services (HHS). Medicare certified providers and suppliers are enrolled in the Medicare program by entering into an agreement with Medicare. They include hospitals, skilled nursing facilities, home health agencies, hospice programs, rural health clinics, critical access hospitals, comprehensive outpatient rehabilitation facilities, laboratories, clinics, rehabilitation agencies, public health agencies, and ambulatory surgical centers. These health and safety requirements are generally called conditions of participation (CoPs) for most providers, requirements for skilled nursing facilities (SNFs), conditions for coverage (CfCs) for ambulatory surgical centers (ASCs) and other suppliers, and conditions for certification for rural health clinics (RHCs). A Medicare-certified provider or supplier that does not substantially comply with the applicable health and safety requirements risks having its participation in the Medicare program terminated.

In accordance with section 1864 of the Act, state health departments or similar agencies, under an agreement with CMS, survey health care providers and suppliers to ascertain compliance with the applicable CoPs, CfCs, conditions of certification, or requirements, and certify their findings to us. Based on these State Survey Agency (SA) certifications, we determine whether the provider or supplier qualifies, or continues to qualify, for participation in the Medicare program.

Section 1865(a) of the Act allows most health care facilities to demonstrate compliance with Medicare CoPs, requirements, CfCs, or conditions for certification through accreditation by a CMS-approved program of a national accreditation body. If an AO is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider or supplier accredited by the AO's CMS-approved accreditation program may be deemed by us to meet the Medicare conditions or requirements.

We are responsible for the review, approval and subsequent oversight of national AOs' Medicare accreditation programs, and for ensuring providers or suppliers accredited by the AO meet the quality and patient safety standards required by the Medicare CoPs, requirements, CfCs, and conditions for certification. Any national AO seeking approval of an accreditation program in accordance with section 1865(a) of the Act must apply for and be approved by CMS for a period not to exceed six years.

The AO must reapply for renewed CMS approval of an accreditation program before the date its approval period expires. This allows providers or suppliers accredited under the program to continue to be deemed to be in compliance with the applicable Medicare CoPs, requirements, CfCs, and conditions for certification. Regulations implementing these provisions are found at 42 CFR 488.1 through 488.9.

We believe that it is necessary to revise the regulations for Medicare-certified providers and providers to add two new requirements for the AOs that accredit certified providers and providers. First, we are proposing at §488.5 to require AOs for Medicare-certified providers and suppliers to include a written statement in their application which states that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the AO's CMS-approved accreditation program, the AO must

continue the facility's current accreditation until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first. We are also proposing to modify the AO oversight regulations at §488.5 by adding new requirements for training for AO surveyors.

B. Proposed Changes to Certain Requirements for Medicare-Certified Providers and Suppliers at Part 488

1. Continuation of Term of Accreditation When A Medicare-Certified Provider or Supplier Decides to Voluntarily Terminate the Services of an Accrediting Organization (§ 488.5)

We propose to add a new regulation at § 488.5(a)(17)(iii), which would require that, with an initial or renewal application for CMS-approval of a Medicare certified provider or supplier accreditation program, an AO must include a written statement agreeing that when a fully accredited, deemed provider or supplier in good standing notifies its AO that it wishes to voluntarily withdraw from the AO's accreditation program, the AO would honor the provider's or supplier's current term of accreditation until the effective date of withdrawal identified by the facility, or the expiration date of the term of accreditation, whichever comes first. We make this proposal because we have received numerous complaints from accredited and deemed facilities in good standing with their current AO stating that once they provide notification to the AO of their intent to voluntary withdrawal their accreditation from that AO, the AO frequently terminates their accreditation immediately without regard to their current accreditation status, up to date payment of fees, contract status, or the facility's requested effective date of withdrawal. Accreditation is voluntary for Medicare certified providers and suppliers that participate in Medicare. It is not required for participation in Medicare. Therefore, we do not believe it is reasonable for AOs to penalize facilities because they choose

to terminate the services of an AO. Medicare certified providers and suppliers may freely choose to demonstrate compliance with the Medicare conditions.by receiving surveys from any CMS-approved AO of their choice, or the SA.

2. Training Requirements for Accrediting Organization Surveyors (§ 488.5(a)(7))

We are proposing to add a new requirement at § 488.5(a)(7) which imposes a new training requirement for surveyors of AO that accredit Medicare certified provider and supplier types by amending the provision at § 488.5(a)(7). We are proposing that all AO surveyors be required to complete the relevant program-specific CMS online trainings initially, and thereafter, consistent with requirements established by CMS for state surveyors. CMS provides a wide variety of comprehensive trainings through an on-demand integrated surveyor training website. These online trainings are available and can be accessed by state and federal surveyors and the public, free of charge, 24 hours a day, 365 days a year. These online trainings are currently publically available for the SA surveyors.

As part of our oversight of the AOs performance, CMS has contracted with the SAs to perform validation surveys on a sample of providers and suppliers (such as hospitals, critical access hospital, ambulatory surgical centers, and home health agencies) accredited by the AOs that accredit Medicare certified providers and suppliers. Validation surveys must be performed by the SA within 60 days of the survey performed by the AO. As a validation survey is performed within 60 days of the AO survey, we believe that the conditions at the hospital or other facility being surveyed would be similar at the time of the validation survey.

The purpose of a validation survey is to compare the survey findings of the AO to the survey findings of the SA to see if there are any disparities. The amount of disparities found in the AO's survey is called the "disparity rate" and is tracked by CMS as an indication of the

quality of the surveys performed by the AO.

CMS has determined that many of the AOs' disparity rates have been consistently high. This means that the AOs have consistently failed to find the same condition level deficiencies in the care provided by the hospital or other providers surveyed that were found by the SA during the validation survey.

We believe that the disparity in findings made by the AO surveyors and those of the SA surveyors can largely be attributed the difference in the training and education provided to the AO surveyors. Each AO is responsible for providing training and education to their surveyors. The surveyor training and education provided varies from AO to AO and is not consistent. CMS provides comprehensive online training to the SA surveyor staff on the CMS Surveyor Training website[104] which are specific to each type of provider of supplier type to be surveyed.

It is our belief that the AO's disparity rate would be decreased if all surveyors took the same training. We believe completion of the same surveyor training by both SA and AO surveyors would increase the consistency between the results of the surveys performed by the SAs and AOs and have a positive impact on the historically high disparity rate. Therefore we are proposing that all AO surveyors be required to take the CMS online surveyor training offered on the CMS website. We would require each AO to provide CMS with documentation which provides proof that each of their surveyors has completed the CMS online surveyor training. If the AO fails to provide this documentation, CMS could place the AO on an accreditation program review pursuant to §488.8(c).

104 https://surveyortraining.cms.hhs.gov/

VIII. Requests for Information

This section addresses two requests for information (RFI). Upon reviewing the RFIs, respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; neither RFI constitutes a Request for Proposal (RFP), application, proposal abstract, or quotation. The RFIs do not commit the U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Failing to respond to either RFI will not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor each RFI announcement for additional information pertaining to the request. Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to these RFIs are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. This RFI should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publically post the comments received, or a summary thereof.

A. Request for Information on Promoting Interoperability and Electronic Healthcare Information Exchange through Possible Revisions to the CMS Patient Health and Safety Requirements for Hospitals and Other Medicare- and Medicaid-Participating Providers and Suppliers

Currently, Medicare- and Medicaid-participating providers and suppliers are at varying stages of adoption of health information technology (health IT). Many hospitals have adopted electronic health records (EHRs), and CMS has provided incentive payments to eligible hospitals, critical access hospitals (CAHs), and eligible professionals who have demonstrated meaningful use of certified EHR technology (CEHRT) under the Medicare EHR Incentive Program. As of 2015, 96 percent of Medicare- and Medicaid-participating non-Federal acute care hospitals had adopted certified EHRs with the capability to electronically export a summary of clinical care.[105] While both adoption of EHRs and electronic exchange of information have grown substantially among hospitals, significant obstacles to exchanging electronic health information across the continuum of care persist. Routine electronic transfer of information post-discharge has not been achieved by providers and suppliers in many localities and regions throughout the Nation.

CMS is firmly committed to the use of certified health IT and interoperable EHR systems for electronic healthcare information exchange to effectively help hospitals and other Medicare- and Medicaid-participating providers and suppliers improve internal care delivery practices, support the exchange of important information across care team members during transitions of care, and enable reporting of electronically specified clinical quality measures (eCQMs). The Office of the National Coordinator for Health Information Technology (ONC)

105 These statistics can be accessed at: https://dashboard.healthit.gov/quickstats/pages/FIG-Hospital-EHR-Adoption.php.

acts as the principal Federal entity charged with coordination of nationwide efforts to implement and use health information technology and the electronic exchange of health information on behalf of the Department of Health and Human Services.

In 2015, ONC finalized the 2015 Edition health IT certification criteria (2015 Edition), the most recent criteria for health IT to be certified to under the ONC Health IT Certification Program. The 2015 Edition facilitates greater interoperability for several clinical health information purposes and enables health information exchange through new and enhanced certification criteria, standards, and implementation specifications. CMS requires eligible hospitals and CAHs in the Medicare and Medicaid EHR Incentive Programs and eligible clinicians in the Quality Payment Program (QPP) to use EHR technology certified to the 2015 Edition beginning in CY 2019.

In addition, several important initiatives will be implemented over the next several years to provide hospitals and other participating providers and suppliers with access to robust infrastructure that will enable routine electronic exchange of health information. Section 4003 of the 21st Century Cures Act (Pub. L. 114-255), enacted in 2016, and amending section 3000 of the Public Health Service Act (42 U.S.C. 300jj), requires HHS to take steps to advance the electronic exchange of health information and interoperability for participating providers and suppliers in various settings across the care continuum. Specifically, Congress directed that ONC "…for the purpose of ensuring full network-to-network exchange of health information, convene public-private and public-public partnerships to build consensus and develop or support a trusted exchange framework, including a common agreement among health information networks nationally." In January 2018, ONC released a draft version of its

proposal for the Trusted Exchange Framework and Common Agreement,[106] which outlines principles and minimum terms and conditions for trusted exchange to enable interoperability across disparate health information networks (HINs). The Trusted Exchange Framework (TEF) is focused on achieving the following four important outcomes in the long-term:

- Professional care providers, who deliver care across the continuum, can access health information about their patients, regardless of where the patient received care.
- Patients can find all of their health information from across the care continuum, even if they do not remember the name of the professional care provider they saw.
- Professional care providers and health systems, as well as public and private health care organizations and public and private payer organizations accountable for managing benefits and the health of populations, can receive necessary and appropriate information on groups of individuals without having to access one record at a time, allowing them to analyze population health trends, outcomes, and costs; identify at-risk populations; and track progress on quality improvement initiatives.
- The health IT community has open and accessible application programming interfaces (APIs) to encourage entrepreneurial, user-focused innovation that will make health information more accessible and improve EHR usability.

ONC will revise the draft TEF based on public comment and ultimately release a final version of the TEF that will subsequently be available for adoption by HINs and their participants seeking to participate in nationwide health information exchange. The goal for stakeholders that participate in, or serve as, a HIN is to ensure that participants will have the ability to seamlessly share and receive a core set of data from other network participants in

106 The draft version of the trusted Exchange Framework may be accessed at: https://beta.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement.

accordance with a set of permitted purposes and applicable privacy and security requirements. Broad adoption of this framework and its associated exchange standards is intended to both achieve the outcomes described above while creating an environment more conducive to innovation.

In light of the widespread adoption of EHRs along with the increasing availability of health information exchange infrastructure predominantly among hospitals, we are interested in hearing from stakeholders on how we could use the CMS health and safety standards that are required for providers and suppliers participating in the Medicare and Medicaid programs (that is, the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RfPs) for Long-Term Care (LTC) Facilities) to further advance electronic exchange of information that supports safe, effective transitions of care between hospitals and community providers. Specifically, CMS might consider revisions to the current CMS CoPs for hospitals, such as: requiring that hospitals transferring medically necessary information to another facility upon a patient transfer or discharge do so electronically; requiring that hospitals electronically send required discharge information to a community provider via electronic means if possible and if a community provider can be identified; and requiring that hospitals make certain information available to patients or a specified third-party application (for example, required discharge instructions) via electronic means if requested.

On November 3, 2015, we published a proposed rule (80 FR 68126) to implement the provisions of the Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) (Pub. L. 113-185) and to revise the discharge planning CoP requirements that hospitals (including short-term acute care hospitals, long-term care hospitals (LTCHs), rehabilitation hospitals, psychiatric hospitals, children's hospitals, and cancer hospitals), critical

access hospitals (CAHs), and home health agencies (HHAs) would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. However, several of the proposed requirements directly address the issue of communication between providers and between providers and patients, as well as the issue of interoperability:

- Hospitals and CAHs would be required to transfer certain necessary medical information and a copy of the discharge instructions and discharge summary to the patient's practitioner, if the practitioner is known and has been clearly identified;
- Hospitals and CAHs would be required to send certain necessary medical information to the receiving facility/post-acute care providers, at the time of discharge; and
- Hospitals, CAHs, and HHAs would need to comply with the IMPACT Act requirements that would require hospitals, CAHs, and certain post-acute care providers to use data on quality measures and data on resource use measures to assist patients during the discharge planning process, while taking into account the patient's goals of care and treatment preferences.

We published another proposed rule (81 FR 39448) on June 16, 2016, that updated a number of CoP requirements that hospitals and CAHs would need to meet in order to participate in the Medicare and Medicaid programs. This proposed rule has not been finalized yet. One of the proposed hospital CoP revisions in that rule directly addresses the issues of communication between providers and patients, patient access to their medical records, and interoperability. We proposed that patients have the right to access their medical records, upon an oral or written request, in the form and format requested by such patients, if it is readily producible in such form and format (including in an electronic form or format when such

medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, including current medical records, within a reasonable timeframe. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

We also published a final rule (81 FR 68688) on October 4, 2016, that revised the requirements that LTC facilities must meet to participate in the Medicare and Medicaid programs. In this rule, we made a number of revisions based on the importance of effective communication between providers during transitions of care, such as transfers and discharges of residents to other facilities or providers, or to home. Among these revisions was a requirement that the transferring LTC facility must provide all necessary information to the resident's receiving provider, whether it is an acute care hospital, an LTCH, a psychiatric facility, another LTC facility, a hospice, a home health agency, or another community-based provider or practitioner (42 CFR 483.15(c)(2)(iii)). We specified that necessary information must include the following:

- Contact information of the practitioner responsible for the care of the resident;
- Resident representative information including contact information;
- Advance directive information;
- Special instructions or precautions for ongoing care;
- The resident's comprehensive care plan goals; and
- All other necessary information, including a copy of the resident's discharge or transfer summary and any other documentation to ensure a safe and effective transition of care.

We note that the discharge summary mentioned above must include reconciliation of the

resident's medications, as well as a recapitulation of the resident's stay, a final summary of the resident's status, and the post-discharge plan of care. In addition, in the preamble to the rule, we encouraged LTC facilities to electronically exchange this information if possible and to identify opportunities to streamline the collection and exchange of resident information by using information that the facility is already capturing electronically.

Additionally, we specifically invite stakeholder feedback on the following questions regarding possible new or revised CoPs/CfCs/RfPs for interoperability and electronic exchange of health information:

- If CMS were to propose a new CoP/CfC/RfP standard to require electronic exchange of medically necessary information, would this help to reduce information blocking as defined in section 4004 of the 21st Century Cures Act?

- Should CMS propose new CoPs/CfCs/RfPs for hospitals and other participating providers and suppliers to ensure a patient's or resident's (or his or her caregiver's or representative's) right and ability to electronically access his or her health information without undue burden? Would existing portals or other electronic means currently in use by many hospitals satisfy such a requirement regarding patient/resident access as well as interoperability?

- Are new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information necessary to ensure patients/residents and their treating providers routinely receive relevant electronic health information from hospitals on a timely basis or will this be achieved in the next few years through existing Medicare and Medicaid policies, the implementing regulations related to the privacy and security standards of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-91), and

implementation of relevant policies in the 21st Century Cures Act?

- What would be a reasonable implementation timeframe for compliance with new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information if CMS were to propose and finalize such requirements? Should these requirements have delayed implementation dates for specific participating providers and suppliers, or types of participating providers and suppliers (for example, participating providers and suppliers that are not eligible for the Medicare and Medicaid EHR Incentive Programs)?

- Do stakeholders believe that new or revised CMS CoPs/CfCs/RfPs for interoperability and electronic exchange of health information would help improve routine electronic transfer of health information as well as overall patient/resident care and safety?

- Under new or revised CoPs/CfCs/RfPs, should non-electronic forms of sharing medically necessary information (for example, printed copies of patient/resident discharge/transfer summaries shared directly with the patient/resident or with the receiving provider or supplier, either directly transferred with the patient/resident or by mail or fax to the receiving provider or supplier) be permitted to continue if the receiving provider, supplier, or patient/resident cannot receive the information electronically?

- Are there any other operational or legal considerations (for example, implementing regulations related to the HIPAA privacy and security standards), obstacles, or barriers that hospitals and other providers and suppliers would face in implementing changes to meet new or revised interoperability and health information exchange requirements under new or revised CMS CoPs/CfCs/RfPs if they are proposed and finalized in the future?

- What types of exceptions, if any, to meeting new or revised interoperability and health information exchange requirements should be allowed under new or revised CMS

CoPs/CfCs/RfPs if they are proposed and finalized in the future? Should exceptions under the QPP, including CEHRT hardship or small practices, be extended to new requirements? Would extending such exceptions impact the effectiveness of these requirements?

We would also like to directly address the issue of communication between hospitals (as well as the other providers and suppliers across the continuum of patient care) and their patients and caregivers. MyHealthEData is a government-wide initiative aimed at breaking down barriers that contribute to preventing patients from being able to access and control their medical records. Privacy and security of patient data will be at the center of all CMS efforts in this area. CMS must protect the confidentiality of patient data, and CMS is completely aligned with the Department of Veterans Affairs (VA), the National Institutes of Health (NIH), ONC, and the rest of the Federal Government, on this objective.

While some Medicare beneficiaries have had, for quite some time, the ability to download their Medicare claims information, in pdf or Excel formats, through the CMS Blue Button platform, the information was provided without any context or other information that would help beneficiaries understand what the data were really telling them. For beneficiaries, their claims information is useless if it is either too hard to obtain or, as was the case with the information provided through previous versions of Blue Button, hard to understand. In an effort to fully contribute to the Federal Government's MyHealthEData initiative, CMS developed and launched the new Blue Button 2.0, which represents a major step toward giving patients meaningful control of their health information in an easy-to-access and understandable way. Blue Button 2.0 is a developer-friendly, standards-based application programming interface (API) that enables Medicare beneficiaries to connect their claims data to secure applications, services, and research programs they trust. The possibilities for better care

through Blue Button 2.0 data are exciting, and might include enabling the creation of health dashboards for Medicare beneficiaries to view their health information in a single portal, or allowing beneficiaries to share complete medication lists with their doctors to prevent dangerous drug interactions.

To fully understand all of these health IT interoperability issues, initiatives, and innovations through the lens of its regulatory authority, CMS invites members of the public to submit their ideas on how best to accomplish the goal of fully interoperable health IT and EHR systems for Medicare- and Medicaid-participating providers and suppliers, as well as how best to further contribute to and advance the MyHealthEData initiative for patients. We are particularly interested in identifying fundamental barriers to interoperability and health information exchange, including those specific barriers that prevent patients from being able to access and control their medical records. We also welcome the public's ideas and innovative thoughts on addressing these barriers and ultimately removing or reducing them in an effective way, specifically through revisions to the current CMS CoPs, CfCs, and RfPs for hospitals and other participating providers and suppliers. We have received stakeholder input through recent CMS Listening Sessions on the need to address health IT adoption and interoperability among providers that were not eligible for the Medicare and Medicaid EHR Incentives program, including long-term and post-acute care providers, behavioral health providers, clinical laboratories and social service providers, and we would also welcome specific input on how to encourage adoption of certified health IT and interoperability among these types of providers and suppliers as well.

B. Request for Information on Price Transparency: Improving Beneficiary Access to Home Health Agency Charge Information

In the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20548 and 20549) and the FY 2015 IPPS/LTCH PPS proposed and final rules (79 FR 28169 and 79 FR 50146, respectively), we stated that we intend to continue to review and post relevant charge data in a consumer-friendly way, as we previously have done by posting hospital and physician charge information on the CMS website.[107] In the FY 2019 IPPS/LTCH PPS proposed rule, we also continued our discussion of the implementation of section 2718(e) of the Public Health Service Act, which aims to improve the transparency of hospital charges. This discussion in the FY 2019 IPPS/LTCH PPS proposed rule continued a discussion we began in the FY 2015 IPPS/LTCH PPS proposed rule and final rule (79 FR 28169 and 79 FR 50146, respectively). In all of these rules, we noted that section 2718(e) of the Public Health Service Act requires that each hospital operating within the United States, for each year, establish (and update) and make public (in accordance with guidelines developed by the Secretary) a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups (DRGs) established under section 1886(d)(4) of the Social Security Act. In the FY 2015 IPPS/LTCH PPS proposed and final rules, we reminded hospitals of their obligation to comply with the provisions of section 2718(e) of the Public Health Service Act and provided guidelines for its implementation. We stated that hospitals are required to either make public a list of their standard charges (whether that be the chargemaster itself or in another form of their choice) or their policies for allowing the public to view a list of those charges in response to an inquiry. In the FY 2019 IPPS/LTCH PPS proposed rule, we took one step to further improve the public accessibility of charge information. Specifically, effective January 1, 2019, we are updating

107 See, for example, Medicare Provider Utilization and Payment Data, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/index.html

our guidelines to require hospitals to make available a list of their current standard charges via the Internet in a machine readable format and to update this information at least annually, or more often as appropriate.

In general, we encourage all providers and suppliers to undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain, and to enable patients to compare charges for similar services. We encourage providers and suppliers to update this information at least annually, or more often as appropriate, to reflect current charges.

We are concerned that challenges continue to exist for patients due to insufficient price transparency. Such challenges include patients being surprised by out-of-network bills for physicians, such as anesthesiologists and radiologists, who provide services at in-network hospitals and in other settings, and patients being surprised by facility fees, physician fees for emergency department visits, or fees for services that are part of the beneficiary's episode of care but that are not otherwise included in a hospital's chargemaster (for example, home health or physical therapy services that follow a hospital stay but are billed separately). We also are concerned that, for providers and suppliers that maintain a list of standard charges, the charge data may not be helpful to patients for determining what they are likely to pay for a particular service or facility encounter. In order to promote greater price transparency for patients, we are considering ways to improve the accessibility and usability of current charge information.

We also are considering potential actions that would be appropriate to further our objective of having providers and suppliers undertake efforts to engage in consumer-friendly communication of their charges to help patients understand what their potential financial liability might be for services they obtain from the provider or supplier, and to enable patients

to compare charges for similar services across providers and suppliers, including when services could be offered in more than one setting. Therefore, we are seeking public comment from all providers and suppliers, including home health agencies, on the following:

- How should we define "standard charges" in the home health setting? Is there one definition for those settings that maintain chargemasters, and potentially a different definition for those settings that do not maintain chargemasters? Should "standard charges" be defined to mean: average or median rates for the items on a chargemaster or other price list or charge list; average or median rates for groups of items and/or services commonly billed together, as determined by the HHA based on its billing patterns; or the average discount off the chargemaster, price list or charge list amount across all payers, either for each separately enumerated item or for groups of services commonly billed together? Should "standard charges" be defined and reported for both some measure of the average contracted rate and the chargemaster, price list or charge list? Or is the best measure of a HHA's standard charges its chargemaster, price list or charge list?

- What types of information would be most beneficial to patients, how can HHAs best enable patients to use charge and cost information in their decision-making, and how can CMS and HHAs help third parties create patient-friendly interfaces with these data?

- Should HHAs be required to inform patients how much their out-of- pocket costs for a service will be before those patients are furnished that service?

How can information on out-of-pocket costs be provided to better support patients' choice and decision-making? What changes would be needed to support greater transparency around patient obligations for their out-of-pocket costs? How can CMS help beneficiaries to better understand how co-pays and co-insurance are applied to each service covered by Medicare? What can be done to better inform patients of their financial obligations? Should HHAs play any role in

helping to inform patients of what their out-of-pocket obligations will be?

- If HHAs were required to provide patients with information on what Medicare pays for a particular service performed by that HHA, what changes would need to be made by HHAs? What burden would be added as a result of such a requirement?

In addition, we are seeking public comment on improving a Medigap patient's understanding of his or her out-of-pocket costs prior to receiving services, especially with respect to the following particular questions:

- How does Medigap coverage affect patients' understanding of their out-of-pocket costs before they receive care? What challenges do HHAs face in providing information about out-of-pocket costs to patients with Medigap? What changes can Medicare make to support HHAs that share out-of-pocket cost information with patients that reflects the patient's Medigap coverage? Who is best situated to provide patients with clear Medigap coverage information on their out-of-pocket costs prior to receipt of care? What role can Medigap plans play in providing information to patients on their expected out-of-pocket costs for a service? What state-specific requirements or programs help educate Medigap patients about their out-of-pocket costs prior to receipt of care?

VII. Collection of Information Requirements

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

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

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2017 National Occupational Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table (Table 57) presents the mean hourly wage rate, fringe benefits costs and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

TABLE 57: MAY 2017 NATIONAL INDUSTRY-SPECIFIC OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES--NAICS 621600 - HOME HEALTH CARE SERVICES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead (100%)($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$33.77	$33.77	$67.54
Physical therapists HHAs	29-1123	$46.19	$46.19	$92.38
Speech-Language Pathologists (SLP)	29-1127	$43.93	$43.93	$87.86
Occupational Therapists (OT)	29-1122	$43.70	$43.70	$87.40

This proposed rule makes reference to associated information collections that are not discussed in the regulation text contained in this document. These proposed changes are associated with the Information Collection Request (ICR) for CMS-10545—Outcome and Assessment Information Set (OASIS) OASIS–C2/ICD–10, approved under OMB control number 0938-1279. We note that on March 12, 2018 we published a notice in the Federal Register seeking public comment on a revision to CMS-10545 (OMB control number 0938-1279), which would modify the OASIS and refer to the revised item set as the OASIS-D upon implementation of the revised data set on January 1, 2019 (83 FR 10730). We are soliciting public comment on additional changes related to when certain OASIS items are required to be completed by HHA clinicians due to the proposed implementation of the patient-driven groupings model (PDGM) for CY 2020, as outlined in section III.F of this proposed rule; and the changes to due to the proposed removal of HH QRP measures beginning with the CY 2021 HH QRP, as outlined in section V.E of this proposed rule.

B. ICRs Regarding the OASIS

We believe that the burden associated with the OASIS is the time and effort associated with data collection and reporting. As of April 1, 2018, there are approximately 11,623 HHAs reporting OASIS data to CMS.

In section V.E.1 of the proposed rule, we are proposing to remove the Depression Assessment Conducted Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. The removal of this measure will not impact collection of information because OASIS Item M1730, which is used to calculate this measure, is also used as a risk adjuster to calculate other OASIS-based outcome measures currently adopted for the HH QRP.[108]

In section V.E.2 of the proposed rule, we are proposing to remove the Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This measure is calculated using OASIS Item M2401, row a at the time point of Transfer to an Inpatient Facility (TOC) and Discharge from Agency — Not to an Inpatient Facility (Discharge). Specifically, we are proposing to remove this one data element at the TOC and Discharge time points.

In section V.E.3 of the proposed rule, we are proposing to remove the Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 1. Measure performance among HHAs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made. This measure is calculated using OASIS

108 The OASIS-based HH QRP outcome measures that use OASIS Item M1730 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), Improvement in Management of Oral Medications (NQF #0176), and Improvement in Status of Surgical Wounds (NQF #0178).

Item M1910 at the time point of SOC/ROC. Specifically, we are proposing to remove this one data element at the SOC/ROC time point.

In section V.E.4 of the proposed rule, we are proposing to remove the Pneumococcal Polysaccharide Vaccine Ever Received Measure from the HH QRP beginning with the CY 2021 HH QRP, under our proposed Factor 3. A measure does not align with current clinical guidelines or practice. This measure is calculated using OASIS Items M1051 and M1056 at the time points of TOC and Discharge. Specifically, we are proposing to remove these two data elements at the TOC and Discharge time points.

In section V.E.5 of the proposed rule, we are proposing to remove the Improvement in the Status of Surgical Wounds Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor 4. A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. The removal of this measure will not impact collection of information because OASIS Items M1340 and M1342 are used as risk adjusters to calculate other OASIS-based outcome measures currently adopted for the HH QRP and OASIS Items M1340 and M1342 are also used for the Potentially Avoidable Events measure Discharged to the Community Needing Wound Care or Medication Assistance that is used by HH surveyors during the survey process.[109] [110]

In sections V.E.6 and V.E.7 of the proposed rule, we are proposing to remove the Emergency Department Use without Hospital Readmission during the First 30 Days of HH

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109 The OASIS-based HH QRP outcome measures that use OASIS Items M1340 and M1342 as a risk adjuster in the calculation of the measure are: Improvement in Bathing (NQF #0174), Improvement in Bed Transferring (NQF #0175), Improvement in Ambulation/Locomotion (NQF #0167), Improvement in Dyspnea, Improvement in Pain Interfering with Activity (NQF #0177), and Improvement in Management of Oral Medications (NQF #0176).

110 Measure specifications can be found in the Home Health Potentially Avoidable Events Measures Table on the Home Health Quality Measures website (https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HomeHealthQualityInits/Downloads/Home-Health-PAE-Measures-Table-OASIS-C2_4-11-18.pdf).

(NQF #2505) Measure and the Rehospitalization during the First 30 Days of HH (NQF #2380) Measure from the HH QRP beginning with the CY 2021 HH QRP under our proposed Factor . A more broadly applicable measure (across settings, populations, or conditions) for the particular topic is available. Because these are both claims-based measures, their removal will not impact collection of information.

Therefore, we are proposing the net reduction of 1 data element at SOC, 1 data element at ROC, 3 data elements at TOC and 3 data elements at Discharge associated with OASIS item collection as a result of the measure removal proposals from the HH QRP.

The OASIS instrument is used for meeting the home health Conditions of Participation, requirements under the HH QRP, and for payment purposes under the HH PPS. As outlined in section III.F of this proposed rule, to calculate the case-mix adjusted payment amount for the PDGM, we are proposing to add collection of two current OASIS items (10 data elements) at the FU time point:

- M1033: Risk for Hospitalization (9 data elements)
- M1800: Grooming (1 data element).

As outlined in section III.F of this proposed rule, several OASIS items would not be needed in case-mix adjusting the period payment for the PDGM; therefore, we are proposing to make 19 current OASIS items (48 data elements) optional at the FU time point:

- M1021: Primary Diagnosis (3 data elements)
- M1023: Other Diagnosis (15 data elements)
- M1030: Therapies (3 data elements)
- M1200: Vision (1 data element)
- M1242: Frequency of Pain Interfering (1 data element)

- M1311: Current Number of Unhealed Pressure Ulcers at Each Stage (12 data elements)
- M1322: Current Number of Stage 1 Pressure Ulcers (1 data element)
- M1324: Stage of Most Problematic Unhealed Pressure Ulcer that is Stageable (1 data element)
- M1330: Does this patient have a Stasis Ulcer? (1 data element)
- M1332: Current Number of Stasis Ulcer(s) that are Observable (1 data element)
- M1334: Status of Most Problematic Stasis Ulcer that is Observable (1 data element)
- M1340: Does this patient have a Surgical Wound (1 data element)
- M1342: Status of Most Problematic Surgical Wound that is Observable (1 data element).
- M1400: Short of Breath (1 data element)
- M1610: Urinary Incontinence or Urinary Catheter Presence (1 data element)
- M1620: Bowel Incontinence Frequency (1 data element)
- M1630: Ostomy for Bowel Elimination (1 data element)
- M2030: Management of Injectable Medications (1 data element)
- M2200: Therapy Need (1 data element)

Therefore, we are proposing the net reduction of 38 data elements at FU associated with OASIS item collection as a result of the implementation of the PDGM for CY 2020.

In summary, under our proposals, there would be a net reduction of 1 data element at SOC, 1 data element at ROC, 38 data elements at FU, 3 data elements at TOC and 3 data elements at Discharge associated with OASIS item collection as a result of the measure removal proposals from the HH QRP and the proposed implementation of the PDGM starting

January 1, 2020.

We assume that each data element requires 0.3 minutes of clinician time to complete. Therefore, we estimate that there would be a reduction in clinician burden per OASIS assessment of 0.3 minutes at SOC, 0.3 minutes at ROC, 11.4 minutes at FU, 0.9 minutes at TOC and 0.9 minutes at Discharge.

The OASIS is completed by RNs or PTs, or very occasionally by occupational therapists (OT) or speech language pathologists (SLP/ST). Data from 2016 show that the SOC/ROC OASIS is completed by RNs (approximately 87 percent of the time), PTs (approximately 12.7 percent of the time), and other therapists, including OTs and SLP/STs (approximately 0.3 percent of the time). We estimated a weighted clinician average hourly wage of $70.75, inclusive of fringe benefits, using the hourly wage data in Table 57. Individual providers determine the staffing resources necessary.

Table 58 shows the total number of assessments submitted in CY 2017 and estimated burden at each time point.

TABLE 58: CY 2017 OASIS SUBMISSIONS AND ESTIMATED BURDEN, BY TIME POINT

Time Point	CY 2017 Assessments Completed	Estimated Burden ($)
Start of Care	6,420,299	-$2,271,180.77
Resumption of Care	1,062,962	-$376,022.81
Follow-up	3,688,651	-$49,584,691.07
Transfer to an inpatient facility	1,925,270	-$2,043,192.79
Death at Home	41,183	0
Discharge from agency	5,249,483	-$5,571,013.83
TOTAL	**18,387,848**	**-$59,846,101.27**

* Estimated Burden ($) at each Time-Point = (# CY 2017 Assessments Completed) x (clinician burden [min]/60) x ($70.75 [weighted clinician average hourly wage]).

Based on the data in Table 58 for the 11,623 active Medicare-certified HHAs in April

2018, we estimate the total average decrease in cost associated with proposed changes with OASIS item collection at $5,148.94 per HHA annually, or $59,846,101.27 for all HHAs annually. This corresponds to an estimated reduction in clinician burden associated with changes to collection of information associated with the OASIS of 72.8 hours per HHA annually, or 845,881.3 hours for all HHAs annually. This decrease in burden would be accounted for in the information collection under OMB control number 0938-1279.

C. ICRs Regarding Home Infusion Therapy

At §486.520, Plan of Care, we propose that all patients must have a plan of care established by a physician that prescribes the type, amount, and duration of infusion therapy services that are to be furnished. This requirement directly implements section 5012 of the 21st Cures Act. Accredited home infusion therapy suppliers are already required by their accrediting bodies to provide all care in accordance with a plan of care that specifies the type, amount, and duration of infusion therapy services to be furnished to each patient; therefore this proposed requirement would not impose a burden upon accredited agencies. Furthermore, all existing home infusion therapy suppliers are already accredited due to existing payment requirements established by private insurers and Medicare Advantage plans. In accordance with the implementing regulations of the PRA at 5 CFR 1320.3(b)(3), this requirement exists even in the absence of a federal requirement; therefore, the associated burden is not subject to the PRA.

D. ICRs Regarding the Approval and Oversight of Accrediting Organizations for Home Infusion Therapy

1. Background

We are proposing to establish a new set of regulations related to the approval and

oversight of accrediting organizations that accredit home infusion therapy suppliers. If finalized, these new regulatory requirements would impose burden on those new AOs that seek approval of their Home Infusion Therapy accreditation program. This burden would include, but is not limited to the time and costs associated with the following activities: (1) preparation and filing of an initial application seeking CMS approval of the AOs home infusion therapy accreditation program; (2) participation in the application review process (that is, meetings, provide additional information and materials that may be required, participate in a site visit, etc.); (3) seeking new accreditation clients; (4) performing on-site surveys, off-site survey audits or the performance of other types of survey activities; (5) participation in CMS ongoing accreditation program review activities; (6) performance of periodic re-accreditation activities; (7) investigation of complaints and performing complaint surveys; (8) administration of the appeals process for providers that have been denied accreditation; (9) staff training, in-services and continuing education; and (10) ensuring that surveyor staff have the proper education, training, and credentials.

The following is a discussion of the potential ICR burdens associated with the proposed home infusion therapy supplier accreditation oversight regulations and well as any PRA exceptions that may apply.

2. Applicable PRA Exception

We believe that the information collection burden associated with the preparation and submission of an initial or renewal application for approval and designation as an home infusion therapy AO and the participation in other accreditation related activities does not meet the definition of "collection of information" as defined in 5 CFR 1320.3(c) because it is "not imposed on 10 or more persons." This information collection burden would be imposed only

on those national AOs that accredit home infusion therapy suppliers.

At this time, there are five CMS-approved AOs and one non-CMS-approved AO that provide accreditation for home infusion therapy suppliers (that is, The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation, and National Association of Boards of Pharmacy). However, these AOs offer home infusion therapy accreditation as part of the deeming accreditation of home health agencies or the home infusion therapy accreditation provided is CMS approved.

In this proposed rule, we have proposed to require that these AO must apply for CMS approval of a home infusion therapy accreditation that is separate and distinct from its home health accreditation program. When we do solicit AOs to accredit home infusion therapy suppliers, we do not anticipate receiving more than the six applications which would be submitted by the existing AOs seeking approval of a home infusion therapy accreditation program, because this is a specialized area of accreditation.

It is possible that the number of AOs that we designate to accredit home infusion therapy suppliers may increase to 10 or more in the future, when we begin accepting applications for home infusion therapy AOs. However, we do not anticipate that the number of AOs that would accredit home infusion therapy suppliers would increase to 10 or more in the foreseeable future.

Should the number of AOs that accredit home infusion therapy suppliers rise to 10 or more, we would prepare and submit an information collection request (ICR) for the burden associated with the accreditation process, as well as obtain OMB approval, prior to accepting additional applications.

E. ICR Regarding Modifications to 42 CFR 488.5

We have proposed to modify the AO approval and oversight regulations for Medicare certified providers and suppliers by adding 2 new requirements. The first proposed new requirement is to added to §488.5(a)(7) and is a requirement that in their application for CMS approval, the AOs that accredited Medicare certified providers and suppliers must include a statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter. The second requirement is to be added as §488.5(a)(18)(iii) and would require that the AOs for Medicare certified providers and suppliers include a written statement in their application for CMS approval agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

1. Burden Associated with CMS Online Training for AO Surveyors

CMS provides a number of online surveyor training modules that are available to the State Survey Agency surveyors. We have proposed to require the AO surveyors to take this training in an attempt to decrease the historically high disparity rate between the AOs survey results and those of the validation surveys performed by the State Survey Agency surveyors.

There are a total of 163 online training programs that are available the State Survey Agency surveyors on the CMS Surveyor Training website. This website provides courses that are general in nature such as "Principles of Documentation Learning Activity – Long Term

Care" and "Basic Writing Skills for Surveyor Staff", infection control, patient safety, Emergency Preparedness. The CMS Surveyor Training website also offers courses related to specific healthcare settings, services, and regulations such as hospitals, CAHs, ASCs, CLIA, Community Mental Health Centers, EMTALA, Federally Qualified Health Centers (FQHCs), Home Health Agencies and OASIS, Hospices, Nursing Homes and the MDS, Outpatient Physical Therapy/Outpatient Speech Therapy. These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace at which the trainee completes the training.

We estimate that each SA surveyor takes approximately 10 of these courses. We further estimate that it would take approximately 3-5 hours to complete each of these courses. Therefore a SA surveyor would incur a time burden of 30-50 hours for the completion of these CMS surveyor training courses. We believe that the surveyors for AOs that accredit Medicare certified providers would need to take the same number and type of surveyor training courses as the SA surveyors (that is - approximately 10 courses). This means that each of the AOs surveyors that takes this training would incur a time burden in the amount of 30-50 hours.

The AOs that accredit Medicare certified providers and suppliers would incur a cost burden for the wages of their surveyors for the time they spend taking these online surveyor training courses. Most surveyors are clinicians such as Registered Nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a Registered Nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). As noted above, we estimated that it would take approximately 30-50 hours for each AO surveyor to complete 10 online surveyor courses. Therefore, the AO would incur wages in the amount of $1,060.80 to $1,768.00 per each

surveyor that completes the CMS online surveyor training. The AO would also incur additional costs for fringe benefits and overhead in the amount of $1,060.80 to $1,768.00 per each surveyor that completes the CMS online surveyor training.

We are not able to accurately estimate to total time and cost burden to each AO for the wages incurred for the time spent by all surveyors of that AO that take the CMS online surveyor training courses, because we do not know exactly how many surveyors each AO has. However, if we estimate that each AO has 15 surveyors, the estimated time burden to each AO associated with this requirement would be 450 to 750 hours ((30 hours x 15 surveyors = 450 hours per all surveyors) and (50 hours x 15 surveyors = 750 hours per all surveyors)). The estimated cost burden to each AO for Medicare certified providers and supplies associated with this requirement would be $31,824 to $53,040 (($1,060.80 x 15 = $15,912) and ($1,768.00 x 15= $26,520) and ($15,912 to $26,520 for fringe benefits and overhead)).

There are currently 9 AOs that accredit Medicare certified providers and suppliers. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 4,050 to 6,750 ((450 hours per all surveyors/AO x 9 AOs = 4,050 hours across all AOs) and (750 hours per all surveyors/AO x 9 AOs = 6,750 hours across all AOs). The estimated cost across all AOs that accredit Medicare certified providers and suppliers would be $763,776 ($15,912 x 9 AOs = $143,208) and ($26,520 x 9 AOs = $238,680) and ($381,888 for fringe benefits and overhead).
However, we believe that the information collection burden associated with the requirement that the surveyors of AOs that accredit Medicare certified providers and suppliers does not meet the definition of "collection of information" as defined in 5 CFR 1320.3(c) because it is "not imposed on 10 or more persons." This information collection burden would be imposed only

on those AOs that accredit Medicare certified providers and suppliers. At this time, there are nine CMS-approved AOs that accredit Medicare certified providers and suppliers (that is, AAAASF, AAAHC, ACHC, AOA-HFAP, Community Health Accreditation Partner (CHAP), CIHQ, DNV-GL, The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT)). Should the number of AOs that accredit Medicare certified providers and suppliers rise to 10 or more, we will seek OMB approval for the burden associated with the accreditation process.

2. Burden Associated with the Requirement for AOs to Continue a Medicare-certified Provider's or Supplier's Accreditation

This proposal would require the AOs for Medicare certified providers and suppliers to include a written statement in their application for CMS approval of their accreditation program, agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

We believe that the AO would incur limited burden associated with this task, because this regulation simply requires that the AOs include a written statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program. All AOs that accredit Medicare certified providers and suppliers are

required to submit an initial application to CMS when they first seek CMS approval and to submit renewal applications to CMS every 6 years thereafter. In accordance wirh 42 CFR 488.5, the AOs are required to provide a number of written acknowledgements with their application. We believe that the AO could add the required written statement to the other written acknowledgements that are included with their applications. As the AO would already be preparing the other acknowledgements required to be submitted with their application, it would be little if any additional burden for the AO to add the required written statement to their application.

We estimate that the required written statement would consist of only 1-2 sentences and would take no more than 5 minutes to prepare. We further believe that clinicians such as registered nurses would prepare the required statement to be included in the AOs application. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the AOs associated with the preparation of the written statement would be approximately $17.68 (15 minutes x $35.36 per hour = $8.84 plus $8.84 in fringe benefits and overhead = $17.68).

There are 9 AOs that accredit Medicare certified providers and suppliers. The estimated time burden across all of these AOs would be 45 minutes (15 minutes x 9 AOs = 135 minutes per all AOs). The estimated cost burden across all AOs that accredit Medicare certified providers and suppliers would be $159.12 ($8.84 x 9 AOs = $79.56 per all AOs + $79.56 for fringe benefits and overhead).

However, we believe that the information collection burden associated with the requirement that the AOs that accredit Medicare certified providers and suppliers provide a

written statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider or supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, does not meet the definition of "collection of information" as defined in 5 CFR 1320.3(c) because it is "not imposed on 10 or more persons." This information collection burden would be imposed only on those AOs that accredit Medicare-certified providers and suppliers. At this time, there are nine CMS-approved AOs that accredit Medicare-certified providers and suppliers (that is, AAAASF, AAAHC, ACHC, AOA-HFAP, Community Health Accreditation Partner (CHAP), CIHQ, DNV-GL, The Joint Commission (TJC), The Compliance Team (TCT)). Should the number of AOs that accredit Medicare certified providers or suppliers rise to 10 or more, we will seek OMB approval for the burden associated with the accreditation process.

F. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. The requirements are not effective until they have been approved by OMB.

We invite public comments on these information collection requirements. If you wish to comment, please identify the rule (CMS-1689-P) and, where applicable, the ICR's CFR citation, CMS ID number, and OMB control number.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at https://www.cms.gov/Regulations-and-

Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.html.

2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.

3. Call the Reports Clearance Office at (410) 786-1326.

See this rule's DATES and ADDRESSES sections for the comment due date and for additional instructions.

VIII. Regulatory Impact Analysis

A. Statement of Need

1. Home Health Prospective Payment System (HH PPS)

Section 1895(b)(1) of the Act requires the Secretary to establish a HH PPS for all costs of home health services paid under Medicare. In addition, section 1895(b) of the Act requires: (1) the computation of a standard prospective payment amount include all costs for home health services covered and paid for on a reasonable cost basis and that such amounts be initially based on the most recent audited cost report data available to the Secretary; (2) the prospective payment amount under the HH PPS to be an appropriate unit of service based on the number, type, and duration of visits provided within that unit; and (3) the standardized prospective payment amount be adjusted to account for the effects of case-mix and wage levels among HHAs. Section 1895(b)(3)(B) of the Act addresses the annual update to the standard prospective payment amounts by the HH applicable percentage increase. Section 1895(b)(4) of the Act governs the payment computation. Sections 1895(b)(4)(A)(i) and (b)(4)(A)(ii) of the Act require the standard prospective payment amount to be adjusted for case-mix and geographic differences in wage levels. Section 1895(b)(4)(B) of the Act requires the establishment of appropriate case-mix adjustment factors for significant variation in costs among different units of services. Lastly, section 1895(b)(4)(C) of the Act requires the establishment of wage adjustment factors that reflect the relative level of wages, and wage-related costs applicable to home health services furnished in a geographic area compared to the applicable national average level.

Section 1895(b)(3)(B)(iv) of the Act provides the Secretary with the authority to implement adjustments to the standard prospective payment amount (or amounts) for

subsequent years to eliminate the effect of changes in aggregate payments during a previous year or years that were the result of changes in the coding or classification of different units of services that do not reflect real changes in case-mix. Section 1895(b)(5) of the Act provides the Secretary with the option to make changes to the payment amount otherwise paid in the case of outliers because of unusual variations in the type or amount of medically necessary care. Section 1895(b)(3)(B)(v) of the Act requires HHAs to submit data for purposes of measuring health care quality, and links the quality data submission to the annual applicable percentage increase. Section 50208 of the BBA of 2018 (Pub. L. 115-123) requires the Secretary to implement a new methodology used to determine rural add-on payments for CYs 2019 through 2022.

Section 1895(b)(2) of the Act and section 1895(b)(3)(A) of the Act, as amended by section 51001(a)(1) and 51001(a)(2) of the BBA of 2018 respectively, require the Secretary to implement a 30-day unit of service, effective for CY 2020, and calculate a 30-day payment amount for CY 2020 in a budget neutral manner, respectively. In addition, section 1895(b)(4)(B) of the Act, as amended by section 51001(a)(3) of the BBA of 2018 requires the Secretary to eliminate the use of the number of therapy visits provided to determine payment, also effective for CY 2020.

Finally, the HHVBP Model applies a payment adjustment based on an HHA's performance on quality measures to test the effects on quality and expenditures.

2. Home Infusion Therapy

Section 1861(iii) of the Act, as added by the Cures Act, sets forth three elements for home infusion therapy suppliers in three areas: (1) ensuring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy

necessary to meet the patient-specific needs, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided, and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home. These provisions serve as the basis for suppliers to participate in Medicare.

Section 1834(u) of the Act serves as the basis for the establishment of a prospective payment system for home infusion therapy covered under Medicare. Section 1834(u)(7) of the Act, as added by BBA of 2018 requires the Secretary to provide a temporary transitional payment to eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs for CYs 2019 and 2020. Under this payment methodology (as described in section VI.C. of this proposed rule), the Secretary would establish three payment categories at amounts equal to the amounts determined under the Physician Fee Schedule established under section 1848 for services furnished during CY 2019 for codes and units of such codes, determined without application of the geographic adjustment.

Section 1834(u)(5)(B) of the Act requires the Secretary to designate organizations to accredit qualified home infusion therapy suppliers furnishing home infusion therapy no later than January 1, 2021. Qualified home infusion therapy suppliers must furnish infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs; ensure the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis; be accredited by an accrediting organization designated and approved by the Secretary; and meet other such requirements as the Secretary deems appropriate.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999), the Congressional Review Act (5 U.S.C. 804(2)), and Executive Order 13771 on Reducing Regulation and Controlling Regulatory Costs (January 30, 2017).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a "significant regulatory action" as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (also referred to as "economically significant"); (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive Order.

A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). The net transfer impact related to the

changes in payments under the HH PPS for CY 2019 is estimated to be $400 million (2.1 percent). The net transfer impact in CY 2020 related to the change in the unit of payment under the proposed PDGM is estimated to be $0 million as section 51001(a) of the BBA of 2018 requires such change to be implemented in a budget-neutral manner. The net transfer impact in CY 2019 related to the Temporary Transitional Payment for Home Infusion Therapy is estimated to be $60 million. The savings impacts related to the HHVBP model as a whole are estimated at $378 million. The cost impact related to OASIS item collection as a result of the proposed implementation of the PDGM and proposed changes to the HH QRP is estimated to be a net $60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020. Finally, the estimated cost impact to each potential home infusion therapy AO is $23,258. We estimate that this rulemaking is "economically significant" as measured by the $100 million threshold, and hence also a major rule under the Congressional Review Act. Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking.

C. Anticipated Effects

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any one year. For the purposes of the RFA, we estimate that almost all HHAs are small entities as that term is used in the RFA. Individuals and states are not included in the definition of a small

entity. The economic impact assessment is based on estimated Medicare payments (revenues) and HHS's practice in interpreting the RFA is to consider effects economically ''significant'' only if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. The majority of HHAs' visits are Medicare paid visits and therefore the majority of HHAs' revenue consists of Medicare payments. Based on our analysis, we conclude that the policies proposed in this rule would result in an estimated total impact of 3 to 5 percent or more on Medicare revenue for greater than 5 percent of HHAs. Therefore, the Secretary has determined that this HH PPS proposed rule would have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. This rule is not applicable to hospitals. Therefore, the Secretary has determined this proposed rule would not have a significant economic impact on the operations of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2018, that threshold is approximately $150 million. This rule is not anticipated to have an effect on State, local, or tribal governments, in the aggregate, or on the private sector of $150 million or more.

Executive Order 13132 establishes certain requirements that an agency must meet when

it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts State law, or otherwise has Federalism implications. We have reviewed this proposed rule under these criteria of Executive Order 13132, and have determined that it will not impose substantial direct costs on state or local governments. If regulations impose administrative costs on private entities, such as the time needed to read and interpret this proposed rule, we must estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the rule, we assume that the total number of unique commenters on this year's proposed rule would be the similar to the number of reviewers of last year's proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we thought that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which would review this proposed rule. We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption. Using the wage information from the BLS for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is $107.38 per hour, including overhead and fringe benefits (https://www.bls.gov/oes/current/oes_nat.htm. Assuming an average reading speed of 250 words per minute, we estimate that it would take approximately 5.3 hours for the staff to review half of this proposed rule, which consists of approximately 160,000 words. For each

HHA that reviews the rule, the estimated cost is $569.11 (5.3 hours x $107.38). Therefore, we estimate that the total cost of reviewing this regulation is $767,729.39 ($569.11 x 1,349 reviewers).

1. HH PPS

a. HH PPS for CY 2019

The update set forth in this rule applies to Medicare payments under HH PPS in CY 2019. Accordingly, the following analysis describes the impact in CY 2019 only. We estimate that the net impact of the policies in this rule is approximately $400 million in increased payments to HHAs in CY 2019. We applied a wage index budget neutrality factor and a case-mix weight budget neutrality factor to the rates as discussed in section III.C.3 of this proposed rule. Therefore, the estimated impact of the 2019 wage index and the recalibration of the case-mix weights for CY 2019 is $0 million. The $400 million increase reflects the distributional effects of the CY 2019 home health payment update of 2.1 percent ($400 million increase), a 0.1 percent increase in payments due to decreasing the FDL ratio in order to target to pay no more than 2.5 percent of total payments as outlier payments ($20 million increase) and a 0.1 percent decrease in payments due to the new rural add-on policy mandated by the BBA of 2018 for CY 2019 ($20 million decrease). The $400 million in increased payments is reflected in the last column of the first row in Table 59 as a 2.1 percent increase in expenditures when comparing CY 2018 payments to estimated CY 2019 payments.

With regards to options for regulatory relief, the rural add-on policy for CYs 2019 through 2022 is statutory and we do not have the authority to alter the methodology used to categorize rural counties or to revise the rural add-on percentages.

b. HH PPS for CY 2020 (Proposed PDGM)

We estimate no net impact of the proposed policies related to the implementation of the PDGM for the CY 2020 HH PPS, as the transition to the 30-day unit of payment is required to be budget neutral. However, since the PDGM eliminates the use of therapy thresholds as a factor in determining payment, HHAs that provide more nursing visits, and thus experience lower margins under the current payment system which may incentivize overutilization of therapy, may experience higher payments. Conversely, HHAs that provide more therapy visits compared to nursing visits, and thus may profit more from the current payment system, may experience lower payments.

c. Proposed Elimination of Recertification Requirement to Estimate How Much Longer Home Health Services will be Required

Sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act require, as a condition of payment, that a physician must certify (and recertify, when home health services are furnished over a period of time) that the individual is eligible for home health services. The regulations at §424.22(b)(2) set forth the content and basis for recertification requirements and states that the recertification statement must indicate the continuing need for services and estimate how much longer the services will be required. This requirement has been longstanding policy that predates the Paperwork Reduction Act of 1995 requirements. Therefore, there is no corresponding Collection of Information that was submitted to the Office of Management and Budget (OMB) for review and approval for the burden estimate for the recertification requirement that the certifying physician must estimate how much longer home health services will be required.

In section III.G. of this proposed rule, we are proposing to eliminate the regulatory requirement as set forth at 42 CFR 424.22(b)(1), that the certifying physician, as part of the

recertification process, include an estimate of how much longer home health services will be required at each home health recertification. While all other recertification content requirements under §424.22 will remain unchanged, the certifying physician would not be required to provide his/her estimation as to how much longer the patient will require home health services on recertifications on and after January 1, 2019. Therefore, we believe this would result in a reduction of burden for certifying physicians by reducing the amount of time physicians spend on the recertification process and we are providing an estimate on the reduction in burden in this proposed rule. All salary information is based on the May 2017 wage data for physicians and surgeons from the Bureau of Labor Statistics (BLS) website at (https://www.bls.gov/oes/current/oes291069.htm) and includes a fringe benefits and overhead worth 100 percent of the base salary.

Using CY 2017 claims, we estimate that of the total number of Medicare home health claims (5.8 million), 37 percent were recertifications (2.1 million) completed by 284,615 certifying physicians.[111] Of those 2.1 million recertifications, we estimate that the time needed to recertify patient eligibility will decrease by 2 minutes per recertification with a total reduction of 69,930 physician hours for all recertifications as a result of eliminating the time estimation statement. Based on the physician's hourly wage of $203.26 as described previously ($101.63 with 100 percent fringe benefits and overhead), this results in an overall annualized cost savings of $14.2 million beginning in CY 2019.

2. HHVBP Model

Under the HHVBP Model, the first payment adjustment applies in CY 2018 based on

111 CY 2017 OASIS assessments matched to Medicare FFS claims (as of March 2, 2018).

PY1 (2016) data and the final payment adjustment will apply in CY 2022 based on PY5 (2020) data. In the CY 2016 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately $380 million (80 FR 68716). In the CY 2017 HH PPS final rule, we estimated that the overall impact of the HHVBP Model from CY 2018 through CY 2022 was a reduction of approximately $378 million (81 FR 76795). We do not believe the changes proposed in this rule would affect the prior estimates.

3. Home Infusion Therapy

a. Health and Safety Standards

Section 5012 of the Cures Act (Pub. L. 114-255), which amended section 1861(s)(2) of the Social Security Act (the Act), established a new Medicare home infusion therapy benefit. Section 1861(iii) of the Act, as added by section 5012 of the Cures Act defines, the Medicare home infusion therapy benefit and covers professional services including nursing services, training and education, and remote monitoring and monitoring services associated with administering certain infusion drugs in a patient's home. This benefit would ensure consistency in coverage for home infusion benefits for all Medicare beneficiaries. Section 1861(iii) of the Act, as added by the Cures Act, sets forth elements for home infusion therapy suppliers in three areas: (1) ensuring that all patients have a plan of care established and updated by a physician that sets out the care and prescribed infusion therapy necessary to meet the patient-specific needs, (2) having procedures to ensure that remote monitoring services associated with administering infusion drugs in a patient's home are provided, and (3) having procedures to ensure that patients receive education and training on the effective use of medications and equipment in the home.

We propose to implement the following requirements for home infusion therapy suppliers--

- Ensure that all patients must have a plan of care established by a physician that prescribes the type, amount and duration of infusion therapy services that are furnished. The plan of care would specify the care and services necessary to meet the patient specific needs.
- Ensure that the plan of care for each patient is periodically reviewed by the physician.
- Ensure that patients have infusion therapy support services at all times through the provision of professional services, including nursing services, furnished in accordance with the plan of care on a 7-day-a-week, 24-hour-a-day schedule.
- Provide patient training and education.
- Provide remote monitoring and monitoring services for the provision of home infusion therapy and home infusion drugs.

All current standards established by AOs already address the proposed requirements set forth in this rule. Furthermore, all existing home infusion therapy suppliers are already accredited by an existing AO for home infusion therapy to meet requirements established by private insurers and Medicare Advantage plans. Therefore, we assume that there would be no new burden imposed on home infusion therapy suppliers in order to meet the proposed health and safety standards. Additionally, we assume that these proposed health and safety provisions would not impose a new burden on home infusion therapy AOs that are likely to apply to be Medicare approved AOs for home infusion therapy because their existing standards would already meet or exceed those that would be established in this rule.

b. Home Infusion Therapy Payment

We estimate that the net impact of the policies in this rule is approximately $60 million

in increased Medicare payments to home infusion suppliers in CY 2019. This increase reflects the cost of providing infusion therapy services to existing DME home infusion therapy beneficiaries (at a 4-hour rate), as the temporary transitional payment applies only to existing Medicare qualified home infusion suppliers (that is, DME suppliers that are enrolled as pharmacies that provide external infusion pumps and supplies are considered eligible home infusion suppliers, as are potential pharmacy suppliers that enroll and comply with the Medicare program's supplier standards (found at 42 CFR 424.57(c)) and quality standards to become accredited for furnishing external infusion pumps and supplies). Prior to the implementation of the temporary transitional payment, home infusion suppliers have not been separately reimbursed for providing these services under the DME benefit. For the temporary transitional payment we do not anticipate an increase in beneficiaries receiving home infusion therapy services as referral patterns are not likely to change significantly due to the inability for other provider types (for example, physicians, HHAs) to become home infusion therapy suppliers prior to CY 2021 and given that existing DME suppliers already provide home infusion therapy services without separate reimbursement.

c. Accreditation of Quality Home Infusion Therapy Suppliers

The requirement for accreditation of home infusion therapy suppliers will cause both the home infusion therapy AOs and the home infusion therapy suppliers to incur costs related to the accreditation process. This section provides a discussion of the estimated time and cost burdens that home infusion therapy suppliers may incur as part of the accreditation process. It also discusses the estimated time and cost burdens that may be incurred by the home infusion therapy AOs to comply with the proposed home infusion therapy AO approval and oversight regulations at §§488.1010 through 488.1050. As the following discussion demonstrates, we

have estimated that each home infusion therapy AO would incur an estimated cost burden in the amount of $23,258 for compliance with the proposed home infusion therapy AO approval and oversight regulations at §§488.1010 through 488.1050.

(1) Burden Incurred by Home Infusion Therapy AOs

Section 1834(u)(5)(B) of the Act requires the Secretary to designate AOs to accredit suppliers furnishing home infusion therapy not later than January 1, 2021. To date, we have not solicited nor approved any AOs to accredit home infusion therapy suppliers as required by section 1834(u)(5)(B) of the Act. Therefore, in this rule we have proposed to publish a solicitation notice in the **Federal Register** seeking national AOs to accredit home infusion therapy suppliers. We propose to publish this solicitation after the publication of the final rule.

The AOs that respond to the solicitation notice would be required to submit an application to CMS requesting CMS-approval of a home infusion therapy accreditation program for Medicare. If CMS approves the AOs application, the home infusion therapy AO would also be required to meet, on an ongoing basis, the requirements set forth in proposed §§488.1010 through 488.1050. The following is a discussion of the burden associated with specific sections of the proposed home infusion therapy AO approval and oversight regulations at §§488.1010 through 488.1050.

(a) Burden for Home Infusion Therapy AOs Associated with Proposed §488.1010

The AOs that accredit home infusion therapy suppliers would incur time and costs burdens associated with the preparation of the application they submit to CMS requesting approval of their home infusion therapy accreditation program. This would include the preparation, gathering or obtaining of all the documentation required in proposed §488.1010(a)(1) through (24).

If the AO has never submitted an application to CMS, we estimate that it would take approximately 70 hours of time to gather, obtain or prepare all documentation required by proposed §488.1010(a)(1) through (23). However, for an existing AO that has previously submitted an application to CMS for any type of accreditation program, we estimate that it would take approximately 45 hours to gather, obtain or prepare all required documentation. We believe that it would take less time for an AO that has previously submitted an application to CMS to prepare an application requesting approval of a home infusion therapy accreditation program because this AO would already be familiar with the application process and requirements. The proposed application requirements for home infusion therapy AOs, set forth at §488.1010(a)(1) through (23), are consistent with those for Medicare-certified providers and suppliers which are set forth at §488.5.

The home infusion therapy AO would incur costs associated with the preparation and submission of the home infusion therapy accreditation program application. The home infusion therapy AO would incur costs for the wages of all AO staff that work on the preparation of the application. We estimate that the AO would have 2 staff work on the preparation of the application. We believe that the AO staff that works on the AOs application would be clinicians such as registered nurses or medical or health services manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm) and the mean hourly wage for a medical or health services manager is $53.69 (https://www.bls.gov/oes/current/oes119111.htm)). Therefore, we estimate that the home infusion therapy AO would incur wages for 45 hours of time by a registered nurse and wages for 45 hours of time by a medical or health services manager in the amount of $8,014.50 (45 hours x $35.36 per hour = $1,591.20) + (45 hours x

$53.69 = $2,416.05 per hour) + ($4,007.25 for fringe benefits and overhead).

As stated previously, we estimate that it would take approximately 70 hours for an AO that has never submitted an application before to prepare and submit their home infusion therapy accreditation program application to CMS. We estimate that the home infusion therapy AO would incur wages for 70 hours of time by a registered nurse and 70 hours of time by a medical or health services manager in the amount of $12,453 (70 hours x $35.36 per hour = $2,475.20) + (70 hours x $53.59 = $3,751.30 + ($6,226,50 for fringe benefits and overhead).

In addition, AOs are required to submit 2 hard copies of their application to CMS in notebooks with dividers and an electronic copy of their application on a thumb drive. Because of this requirement, the home infusion therapy AO would incur costs for the notebooks, dividers, thumb drive, photocopying, paper and ink, and postage costs for mailing the notebooks with the hard copies of the application to the CMS Central Office. We estimate that these costs would be no more than $250.

At this time, there are six AOs that accredit home infusion therapy suppliers (that is - The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). The home infusion therapy accreditation offered by these AOs is offered as part of the deeming accreditation of a home health accreditation program and has not been approved under the requirements of section 1834(u)(5)(A) of the Act. Therefore, we are proposing that, in order for the home infusion therapy suppliers accredited by these AOs to continue to receive payment for the home infusion therapy services furnished to Medicare beneficiaries, these AOs must obtain Medicare approval for a home infusion therapy accreditation program. If all of

these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, the cost incurred across all of these potential home infusion therapy AOs for the preparation and submission of their applications would be $48,087 ($4,007.25 x 6 AOs = $24,043.50) + ($24,043.50 for fringe benefits and overhead).

To obtain this CMS approval, we are proposing that these AOs would be required to submit an application to CMS seeking approval of a home infusion therapy accreditation program that meets the requirements set forth in the proposed new home infusion therapy AO approval and oversight regulations set forth at §§488.1010.1 through 488.1010.24 and the proposed new home infusion therapy health and safety regulations at 42 CFR part 466, subpart I. We have further proposed that the home infusion therapy accreditation programs submitted to CMS for approval by the existing home infusion therapy AOs be consistent with the requirements of section 5102 of the 21st Century CURES Act and section 1861(iii) of the Act. We would also require that the home infusion therapy programs submitted by these AOs be separate and distinct from the AOs home health deeming accreditation program.

The AOs that currently provide home infusion therapy accreditation would incur the time and costs associated with the preparation of the CMS application and required supporting documentation. We estimate that it would take these AOs approximately 45 hours to prepare their applications and supporting documentation because they have previously submitted applications for approval of their home health accreditation programs. The existing AOs that accredit home infusion therapy suppliers would also incur costs for the wages for all AO staff involved with the preparation and submission of the application. The AO would also incur costs for printing the hard copies of the application, ink and paper, notebooks and dividers, and postage.

(b) Burden for Home Infusion Therapy AOs Associated with Proposed §488.1030

In accordance with proposed §488.1030(b) CMS would perform a comparability review if CMS makes changes to the home infusion therapy AO approval and oversight regulations or home infusion therapy health and safety regulation. The purpose of the comparability review is to allow CMS to assess the equivalency of a home infusion therapy AO's accreditation standards with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare home infusion therapy accreditation requirements.

Proposed §488.1030(b)(1) would provide that if CMS were to make changes to the home infusion therapy AO approval and oversight accreditation regulations or the home infusion therapy health and safety regulations, CMS would send a written notice of the changes to the home infusion therapy AOs. Proposed §488.1030(b)(2) would provide that CMS would provide a deadline of not less than 30 day by which the AO must submit its revised home infusion therapy accreditation program standards to CMS

Proposed §488.1030(b)(2) would require the home infusion therapy AOs to revise their home infusion therapy accreditation standards so as to incorporate the changes made by CMS. The AO must submit their revised home infusion therapy accreditation program standards to CMS by the deadline specified in CMS' written notice. The AO may submit a request for an extension of the submission deadline, so long as the request is submitted prior to the original submission deadline.

The home infusion therapy AOs would incur a time burden associated with the time required for the AO staff to review CMS' notice of the revisions to the home infusion therapy AO approval and oversight accreditation standards or home infusion therapy health and safety standards. We estimate that it would take no more than 1 hour for the AO to review the notice

from CMS notifying the AO of the changes to the AO approval and oversight regulations or health and safety regulation.

The home infusion therapy AOs would incur a cost burden for the wages of the AO staff that are involved with reviewing the CMS notice and the preparation of the home infusion therapy AO's revised accreditation program standards. We believe that the AO staff that would review the notice from CMS regarding changes to the CMS home infusion therapy regulations would be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the home infusion therapy AO would incur a cost burden in the amount of $ 70.72 for the preparation of the response to CMS (1 hour x $35.36 per hour = $35.36) + ($35.36 for fringe benefits and overhead).

The home infusion therapy would also incur a cost burden for the wages of the AO staff for the time spent preparing the AOs revised home infusion therapy accreditation standards. However, we are unable to accurately estimate this cost because the amount of wages incurred would be dependent on the amount of time spent by the AO staff preparing the AOs revised accreditation standards.

We believe that the AO staff that would prepare the home infusion therapy AOs revised home infusion therapy accreditation standards would be a clinician such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). If we were to estimate that it would take 5 hours for the home infusion therapy AO to prepare the revised home infusion therapy accreditation standards, the estimated cost burden to the AO would be $353.60 (5 hours x $35.36 per hour = $176.80) + ($176.80 for fringe benefits and

overhead).

At this time, there are six AOs that accredit home infusion therapy suppliers (that is - The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). The home infusion therapy accreditation offered by these AOs is offered as part of the deeming accreditation of a home health accreditation program and has not been approved under the requirements of section 1834(u)(5)(A) of the Act. If all of these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, the cost incurred across all of these AOs for the preparation of revised accreditation standards would be $2,121.60 ($176.80 x 6 AOs = $1,060.80) + ($1,060.80 for fringe benefits and overhead).

As provided by proposed §488.1030(b)(4), a home infusion therapy AO may request an extension of the deadline by which they must submit their revised accreditation home infusion therapy standards, so long as the extension request is submitted prior to the submission deadline. If the home infusion therapy AO requested an extension of the submission deadline, the AO would incur burden for the time required to prepare and submit the deadline extension request, however, we believe this burden would be minimal. We believe that the extension request could be sent in the form of an email to CMS, would consist of no more than a few paragraphs and would take no more than 15 minutes to prepare and send.

The AO would incur a cost burden for the wages for the AO staff who prepares the extension request. We believe that this email would be sent by an administrative assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive

administrative assistant is $28.56 (https://www.bls.gov/oes/current/oes436011.htm). We estimate that the AO would incur a cost burden for wages related to the preparation and sending of the extension request to CMS in the amount of $14.28. ($28.56 x 15 minutes = $7.14) + ($7.14 for fringe benefits and overhead).

At this time, there are six AOs that accredit home infusion therapy suppliers (that is - The Joint Commission (TJC), Accreditation Commission for Health Care (ACHC), The Compliance Team (TCT), Community Health Accreditation Partner (CHAP), Healthcare Quality Association on Accreditation (HQAA), and National Association of Boards of Pharmacy). If all of these six AOs were to submit applications to CMS for approval of a home infusion therapy accreditation program, they could become CMS-approved home infusion therapy AOs. It is unlikely that all of the AOs would submit a request for an extension of the deadline to submit their revised accreditation standards to CMS. However, if this were to occur, the cost incurred across all of these AOs for the preparation of the extension requests by each home infusion therapy AO would be $85.68 ($7.14 x 6 AOs = $42.84) + ($42.84 for fringe benefits and overhead).

Proposed §488.1030(b)(7) would provide that if CMS were to make significant substantial changes to the home infusion therapy AO approval and oversight accreditation standards or the home infusion therapy health and safety standards, we may require the home infusion therapy AOs to submit a new application for approval of their revised home infusion therapy accreditation programs. If this were to occur, the home infusion therapy AOs would incur a time burden for the time associated the preparation of the AOs new application.

We estimate that it would take the home infusion therapy AO approximately 45 hours to prepare and submit their new application to CMS. This would include the time and costs

required to gather and prepare the required supporting documentation to go with the application. We believe that the home infusion therapy AOs would already be familiar with the CMS application process and would be able to use their previous application and supporting documentation with updates, therefore, the reapplication process would be less burdensome.

The home infusion therapy AO would also incur costs associated with the preparation and submission of a new application. The home infusion therapy AO would incur costs for the wages of all AO staff that work on the preparation of the application. We estimate that the AO would have 2 staff persons work on the preparation of the application. Furthermore, we believe that the AO staff that works on the AOs application would be clinicians such as a registered nurse and a medical or health services manager. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 ((https://www.bls.gov/oes/current/oes291141.htm). and the mean hourly wage for a medical or health services manager is $53.69 ((https://www.bls.gov/oes/current/oes119111.htm). Therefore, we estimate that the home infusion therapy AO would incur wages for 45 hours of time by a registered nurse and 45 hours of time by a medical or health services manager in the amount of $$8,014.50 (45 hours x $35.36 per hour = $1,591.20) + (45 hours x $53.69 = $2,416.05 per hour) + ($4,007.25 for fringe benefits and overhead). The cost across all the 6 potential home infusion therapy AOs would be $48,087 ($4007.25 x 6 AOs = $24,043.50) + ($24,043.50 for fringe benefits and overhead).

In addition, AOs are required to submit 2 hard copies of their application to CMS in notebooks with dividers and an electronic copy of their application on a thumb drive. Because of this requirement, the home infusion therapy AO would incur costs for the notebooks, dividers, thumb drive, photocopying, paper and ink, and postage costs for mailing the

notebooks with the hard copies of the application to the CMS Central Office. We estimate that these costs would be no more than $250.

In accordance with proposed §488.1030(c), CMS will perform a standards review when the home infusion therapy AO makes updates to its accreditation standards and surveys processes. Proposed §488.1030(c)(1) would require that when a home infusion therapy AO proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy AO must submit its revised accreditation standards and survey processes to CMS for review, at least 60 days prior to the proposed implementation date of the revised standards. Proposed §488.1030(c)(3) would require that the home infusion therapy AO provide CMS with a detailed description of the changes that are to be made to the AO's home infusion therapy accreditation standards, requirements and survey processes and a detailed crosswalk (in table format) that states the exact language of the organization's revised accreditation requirements and the applicable Medicare requirements for each. Proposed §488.1030(c)(4) would provide that CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. Proposed §488.1030(c)(5) would provide that if a home infusion therapy AO implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with proposed §488.1030(c)(d).

The burden to the home infusion therapy AO associated with the standards review

includes the time required for the home infusion therapy AO to prepare its revised accreditation standards and detailed crosswalk for submission to CMS and submit them to CMS for review. This burden would also include the time required for the AO staff to read and respond to CMS' written response. It is important to note that we do not include in our burden estimate the time that would be spent by the home infusion therapy AO in making voluntary revisions to their accreditation standards that are not required by CMS nor prompted by a regulatory change.

The home infusion therapy AO would also incur costs for the wages of the AO staff involved with the preparation of the AO's revised home infusion therapy accreditation standards and the detailed crosswalk for submission to CMS. The AO would also incur costs for wages for the time the AO staff spent reviewing CMS' response. However, the AO could send their revised accreditation standards to CMS via email, therefore the AO would not incur costs for postage.

We are not able to accurately estimate the total time and cost burden associated with the standards review because the time required for the home infusion therapy AO to prepare its revised home infusion therapy accreditation standards and detailed crosswalk would depend on the extent of the revision the AO has made to its home infusion therapy accreditation standards or survey processes. The burden would also depend of the content and length of CMS' response letter. However, we do estimate that the preparation of the home infusion therapy AOs revised accreditation standard and detailed crosswalk for submission to CMS would take no less than 5 hours.

We believe that the AO staff that would prepare the home infusion therapy AOs revised home infusion therapy accreditation standards and detailed crosswalk for submission to CMS would be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics,

the mean hourly wage for a non-industry specific registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, if we were to estimate that this task would take 5 hours to complete, the cost burden to the home infusion therapy would be $353.60 (5 hours x $35.36 per hour = $176.80) + ($176.80 for fringe benefits and overhead).

We further estimate that it would take the home infusion therapy AO approximately 30 minutes for the home infusion therapy AO to review the CMS response to their submission of the revised home infusion therapy accreditation standards and detailed crosswalk. We believe that a clinician such as a registered nurse would review the CMS response letter. Therefore, the cost burden to the home infusion therapy AO associated with this task would be $ 53.04 (45 minutes x $35.36 per hour = $26.52) + ($26.52 for fringe benefits and overhead).

It is important to note that we have not calculated this burden across all of the potential home infusion therapy AOs. We have not done so because the submission of revised home infusion therapy accreditation standards by a home infusion therapy AO would only occur on an occasional basis and would never be done by all 6 potential AOs at the same time.

In accordance with proposed §488.1030(d), CMS may perform a home infusion therapy accreditation program review if a comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy AO's CMS-approved home infusion therapy accreditation program with the requirements of the proposed home infusion therapy AO approval and oversight regulation at 42 CFR part 488, subpart L. If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy AO indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice would provide all of the following information:

• A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

• A description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy accrediting organization to offer factual information related to CMS' findings.

• A description of the possible actions that may be imposed by CMS based on the findings of the home infusion therapy accreditation program review.

• The actions the home infusion therapy accrediting organization must take to address the identified deficiencies

• A timeline for implementation of the home infusion therapy accrediting organization's corrective action plan, not to exceed 180 calendar days after receipt of the notice that CMS is initiating a home infusion therapy accreditation program review.

Proposed §488.1030(d)(3) would provide that CMS will monitor the performance of the AO's home infusion therapy and the implementation of the corrective action plan during a probation period of up to 180 days. Proposed §488.1030(d)(4) would provide that if CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of the proposed regulations at §§488.1010 through 488.1050, CMS may place the home infusion therapy AO's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the period described in §488.1030(d)(1)(iv).

The time burden associated with the home infusion therapy accreditation program

review includes the time burden associated with the AO's review of CMS' written notice which indicates that the home infusion therapy AO's CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The time required for the review of the CMS letter will depend on the length of CMS' finding. However, we estimate it would take no more than 60 minutes to review this letter.

The AO would incur costs for the wages of the AO staff who performs the review of the CMS letter. We believe that an AO staff person with a clinical background such as a registered nurse would review the CMS letter. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36(https://www.bls.gov/oes/current/oes291141.htm). Therefore, we estimate that the cost burden to the home infusion therapy AO associated with the review of the CMS letter would be approximately $70.72 (1 hour x $35.36 = $35.36) + ($35.36 for fringe benefits and overhead).

There is further burden associated with the requirement that the AO prepare and submit a written response to the CMS letter and a corrective action plan. However, we are unable to accurately estimate the time burden associated with this task because the amount of time required for the home infusion therapy AO to prepare the response letter and corrective plan would be dependent on the number and type of findings identified in CMS' letter.

However, we believe that an AO staff person with a clinical background such as a registered nurse would prepare the home infusion therapy AO's written response to the CMS letter and a corrective action plan. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36(https://www.bls.gov/oes/current/oes291141.htm). If we were to estimate that it would take the home infusion therapy AO 3 hours to prepare and submit a written response to the CMS letter and a corrective action plan, the estimated cost

burden to the home infusion therapy AO associated with this task would be $212.16 (3 hours x $35.36 = $106.08) + ($106.08 for fringe benefits and overhead). Proposed §488.1030(d)(2) provides that CMS would review and approve the AO's plan of correction within 30 days of receipt. If CMS requires the home infusion therapy AO to make changes to their corrective action plan as a condition of approval, the AO would incur burden for the time required to make the required revisions to their plan of correction and resubmit it to CMS.

The home infusion therapy AO would incur a time burden for the time spent by the AO staff making corrections to the AOs corrective action plan. We are unable to accurately estimate how long it would take for the AO to revise its corrective action plan because the revision to be made to the corrective action plan would be dependent on the extent of the correction requested by CMS.

However, we believe that an AO staff person with a clinical background such as a registered nurse would make the corrections to the AOs corrective action plan. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). So, if we were to estimate that it would take the home infusion therapy AO 2 hours to prepare and submit a written response to the CMS letter and make any necessary revision to the corrective action plan, the estimated cost burden to the home infusion therapy AO associated with this task would be $141.44 (2 hours x $35.36 per hour = $70.72) + ($70.72 for fringe benefits and overhead).During the 180 day probationary period, CMS is likely to require the home infusion therapy AO to submit periodic progress reports and participate in periodic telephone to monitor the home infusion therapy AOs progress. The home infusion therapy AO would incur burden for the time required to prepare and submit an initial progress report. We estimate that the initial progress report would take

approximately one hour to prepare. We further estimate that the burden associated with the preparation and submission of subsequent progress reports would be less than that for the initial progress report because the AO would be able to modify or update their initial or previous progress report. We estimate that it would take approximately 1 hour for the AO staff to prepare the initial progress report and 30 minutes for the AO staff to prepare subsequent progress reports. If CMS were to require the AO to submit one progress report per month during the entire 180 day probation period (6 months), the AO would have to submit 1 initial progress report and 5 subsequent progress reports. Therefore, we estimate that the AO would incur a time burden in the amount of 3.5 hours for the submission of all progress reports during the 180 day probation period. The AO would also incur a cost burden for the wages of the AO staff person who is involved in the preparation and submission of the progress reports. We believe that the initial and subsequent progress reports would be prepared by person with a clinical background such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). We estimate that the home infusion therapy AO would incur a cost burden in the amount of $247.52 for the preparation of the progress reports during the 180 day probation period ($3.5 hours x 35.36 per hour = $123.76) + ($123.76 for fringe benefits and overhead).

The home infusion therapy AO would also incur burden associated with the time required to participate in the periodic phone calls with CMS. We are not able to accurately estimate the amount of time that would be required for these periodic phone calls because we do not know how often the AO would be required to participate in phone calls with CMS or how long these phone calls would last. However, we do not believe that these phone calls

would be held more often that monthly or last more than one hour. The AO would incur costs for the wages of all AO staff that participate in the periodic telephone calls. We are not able to accurately estimate the total cost burden for wages that would be incurred by the home infusion therapy AO at this time, because we do not know who from the AO would be attending these meetings.

If we were to estimate that these phone calls were to be held on a monthly basis during the 180 day probation period for a period of one hour period per call, the home infusion therapy AO would incur a time burden in the amount of 6 hours per each staff member that participates in these phone calls. We believe that the AO would have a minimum of 3 staff that are clinicians, such as registered nurses, participate on the call. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/ooh/healthcare/registered-nurses.htm). Therefore, the cost burden to the home infusion therapy AO for participation in the monthly telephone calls would be $1,272.96 ((3 AO staff x $35.36 per hour = $106.08 per call per all staff / $106.08 per call per all staff x 6 calls = $636.48 total wages per all staff per all calls) + ($636.48 for fringe benefits and overhead)).

At or near the end of the first 180 day probationary period, CMS will make a decision as to whether the home infusion therapy AO has successfully come into compliance with the home infusion therapy regulations, or whether the AO has failed to do so. Proposed §488.1030(d)(4) would provide that if CMS finds that the home infusion therapy AO has failed to properly implement the plan of correction and come into compliance with the requirements of the proposed home infusion therapy AO approval and oversight regulation or the proposed home infusion therapy health and safety regulations, CMS may place the home infusion therapy

AO's on an additional probation period of up to 180 calendar days. If this were to occur, the AO would incur the same or similar time and cost burdens as in the initial 180 day probationary period. (See previous estimates for the estimated time and cost burden associated with the 180-day probationary period).

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under §488.1030(d) across all of the potential home infusion therapy AOs. We have not done so because the act of CMS placing a home infusion therapy AO on an accreditation program review would only occur on a sporadic and as needed basis. There would **never** be a situation in which all 6 potential AOs would be under an accreditation program review at the same time.

(c) Burden for Home Infusion Therapy AOs Associated with Proposed § 488.1035

Proposed § 488.1035 titled "Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization" would require that the home infusion therapy AO carry out certain activities and submit certain documents to CMS on an ongoing basis. Proposed § 488.1035(a) would require the home infusion therapy AO to submit the following documents to CMS: (1) copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements); (2) notice of all accreditation decisions; (3) notice of all complaints related to providers or suppliers; (4) information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation; (5) the home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to

the past year's accreditation activities and trends; (6) notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process.

We believe that there would be little burden associated with this requirements for several reasons. First, while the home infusion therapy AOs would be required to provide copies of all survey reports and any survey-related information that CMS may require, the AOs would only be required to provide this information upon request. CMS may not request the home infusion therapy AO to submit this information if there are no compliance concerns. Second, we believe the home infusion therapy AO would keep these records in the normal course of their business as a home infusion therapy AO and would store the survey records in electronic format. As the AO already has this information prepared and stored in an electronic format, it would place little if any burden on the home infusion therapy AO to provide this information to CMS. We believe that the AO could send this information to CMS via email and attach the survey record electronic files to the email.

We estimate that it would take approximately 30 minutes to locate the required survey information files and approximately 15 minutes for the AO staff to prepare an email to CMS and attach the electronic files to the email. We believe that the person at the AO that would prepare the email sending the survey information to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/ooh/healthcare/registered-nurses.htm). . Therefore, the cost burden to the home infusion therapy AO associated with the preparation and submission of the survey reports and information to CMS would be $53.04 (30 minutes to locate information requested by CMS x $35.36 per hour = $17.68) + (15 minutes x $35.36 =

$8.84) + ($26.52 for fringe benefits and overhead). The estimated cost across the potential 6 home infusion therapy AOs for these tasks would be $318.24 ($53.04 x 6 home infusion therapy AOs = $318.24).

Proposed §488.1035(a)(2) would require the home infusion therapy AO to provide CMS with notice of all accreditation decisions made for each home infusion therapy supplier that files an application for accreditation. This would consist of a list of each home infusion therapy supplier that had filed an application with the home infusion therapy AO for accreditation and the accreditation decision made by the AO.

We believe that these accreditation decisions would be made by the AO in the normal course of the AOs business of performing accreditation of home infusion therapy suppliers. We further believe that there would be little burden associated with the requirement that the AO provide CMS with a list of the accreditation decisions made by the AO as this is information that would be readily available to the AO and that could quickly and easily be provided to CMS via email. We estimate that it would take approximately 15 minutes for the home infusion AO to gather the required accreditation decision information in preparation for sending it to CMS.

We believe that this information can be sent to CMS via email and estimate that it would take an additional 15 minutes for the AO staff to prepare an email to CMS and attach the electronic files containing the accreditation decision information to the email. We believe that the person at the AO who would prepare the accreditation decision information and prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation and submission of the survey reports

and information to CMS would be $35.36 (15 minutes x $35.36 per hour = $8.84) and (15 minutes x $35.36 = $8.84) + ($17.68 for fringe benefits and overhead). The estimated cost across the potential 6 home infusion therapy AOs for these tasks would be $212.16 ($35.36 x 6 home infusion therapy AOs = $212.16).

Section 488.1035(a)(3) would require the AO to report complaint information to CMS. Complaint information is typically reported to CMS by other AOs by email on a monthly basis for the previous month. The contents of the complaint information reported to CMS would depend on whether the AO had received any complaints during the previous month. For example, if the AO received no complaint during the previous month, this email could consist of a sentence stating that the AO had received no complaints If the AO had received one or more complaints during the previous month, the AO would be required to provide information about the nature of each complaint, a description of the investigation performed, a description of how the complaint was resolved and the date resolved.

We believe that there would be little burden associated with the reporting of complaint information by the home infusion therapy AO to CMS for several reasons. First, we estimate that the home infusion therapy AOs will rarely receive complaints about their accredited home infusion therapy suppliers. Second, we believe that the home infusion therapy AO will store information about any complaints received in an electronic format. Therefore, complaint information can be reported by the home infusion therapy AO to CMS via email. We estimate that the preparation of the complaint information email would take only no more than 15 minutes to prepare and send.

We believe that the person at the AO who would prepare the complaint information email and sent it to CMS would most likely be a clinician such as a registered nurse. According

to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm) Therefore, the estimated monthly cost burden to the home infusion therapy AO associated with the submission of complaint information to CMS would be $17.68 (15 minutes x $35.36 per hour = $8.84) + ($8.84 for fringe benefits and overhead). The estimated yearly burden to the home infusion therapy AO for this task would be $212.16 ($17.68 per month x 12 months per year = $212.16 per year).

The estimated monthly cost across the potential 6 home infusion therapy AOs for these tasks would be $106.08 ($17.68 x 6 home infusion therapy AOs = $106.08). The estimated yearly cost across the 6 potential home infusion therapy AOs would be $1,272.96 ($17.68 x 6 AOs = $106.08 per all AOs per month / $106.08 per year x 12 months per year = $1,272.96. Proposed §488.1035(a)(4) would require the AO to provide CMS with information about all home infusion therapy accredited suppliers against which the home infusion therapy AO has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation. The information to be sent to CMS would simply consist of a list of the home infusion therapy suppliers and the type of remedial or adverse action taken.

We expect that when a home infusion therapy AO takes remedial or adverse action against its accredited supplier, the AO would prepare documentation which states the action taken and the reason this action was taken. We further believe that the AO would store this information electronically. This would enable the AO to send the required information to CMS via email. Therefore, we believe that there would be little burden associated with this requirement.

We believe that the home infusion therapy AOs could send information about adverse or remedial actions they have taken against their accredited suppliers via email. We estimate that

it would take approximately 30 minutes for a home infusion therapy AO to prepare a report about the adverse or remedial actions taken against its accredited suppliers and approximately 15 minutes to prepare an email to CMS, attach the electronic file with the required information and send it to CMS. The home infusion therapy AOs would be required to report this information to CMS on a monthly basis.

The AO would incur a cost burden for the wages of the AO staff for the time spent preparing the report of the adverse or remedial action taken against the AO's accredited home infusion therapy suppliers and the time spent preparing the email to CMS. We believe that the person at the AO who would prepare the report of adverse or remedial action taken and prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost monthly cost burden to the home infusion therapy AO associated with the submission of information about the adverse or remedial action taken by the home infusion therapy AO against its accredited home infusion therapy suppliers to CMS would be $53.04 (30 minutes x $35.36 per hour = $17.68 + (15 minutes x $35.36 per hour = $8.84) + ($26.52 for fringe benefits and overhead). The estimated yearly cost burden to the home infusion therapy AO for this task would be $636.48 ($53.04 per month x 12 months per year = $636.48 per year).

The estimated monthly cost across the potential 6 home infusion therapy AOs for these tasks would be $318.24 ($53.04 x 6 home infusion therapy AOs = $318.24). The estimated yearly cost across the 6 potential home infusion therapy AOs would be $3,818.88 ($53.04 x 6 AOs = $318.24 per all AOs per month / $318.24 per year x 12 months per year = $3,818.88.

Proposed §488.1035(a)(5) would require the home infusion therapy accrediting

organization to provide, on an annual basis, summary data specified by CMS that relates to the past year's accreditation activities and trends. This summary data might include information such as the total number of complaints received during the year, the total number of immediate jeopardy situations found during the year, and the total number of deficiencies cited. We believe this is information that the AO would collect and document throughout the year in the normal course of business. We further believe that the home infusion therapy AO would prepare this year end summary data for their own informational, quality improvement, and research purposes.

We believe that there would be little, if any time burden associated with the submission of the documents and information required by proposed §488.1035(a)(5) by the home infusion therapy AOs to CMS, because these are documents which the AO would keep in the normal course of business, therefore these documents would be easily accessible to the home infusion therapy AO. Title 5 CFR 1320.3(b)(2) states that the time, effort, and financial resources necessary to comply with a collection of information that would be incurred in the normal course of their activities (for example in compiling and maintaining business records) will be excluded from the burden if the agency demonstrates that the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary. Further, we believe that most, if not all of the home infusion therapy AOs would store these documents electronically and would be able to send them electronically to CMS via email.

The home infusion therapy AO would incur a time burden for the preparation and submission of the annual summary data to CMS. We estimate that it would take approximately 60 minutes for the home infusion therapy AO to locate the required annual summary data information and prepare it for submission to CMS. We further estimate that it would take an

additional 15 minutes to prepare an email to CMS and attach the electronic files containing the summary data.

The home infusion therapy AO would incur a cost burden for the wages of the AO staff who prepares that summary data for submission to CMS and prepares the email to in which the annual summary data are submitted to CMS. We believe that the person at the AO who would prepare the summary data for submission to CMS and also prepare the email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the submission of summary data to CMS would be $88.40 (60 minutes x $35.36 per hour = $35.36) + (15 minutes x $35.36 per hour = $8.84) + ($44.20 for fringe benefits and overhead). The estimate cost burden across the 6 potential home infusion therapy AOs for this task would be $530.40 ($88.40 x 6 potential home infusion therapy AOs = $530.40).

Proposed § 488.1035(b) would require that within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS. The time burden associated with this requirement would be the time required for an AO staff person to review the notification from CMS about the change in home infusion therapy accreditation program requirements and the time required for the AO staff person to compose and send an acknowledgement email to CMS.

We estimate the time required for the AO staff to review the notice of a change in CMS requirements would be 1 hour. We further estimate that the time that would be required to prepare and submit the acknowledgement of receipt of the CMS notice would be approximately

15 minutes because this notice could be sent to CMS via email and would only consist of 1-2 paragraphs.

The home infusion therapy AO would incur a cost burden for the wages of the staff for the time required to review the notice from CMS of the change in CMS requirements. The home infusion therapy AO would incur a cost burden for the wages of the staff for the time required to prepare the acknowledgement and submits it to CMS. We believe that the person at the AO who would prepare the email to CMS acknowledging receipt of the CMS notice would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm).

The estimated cost burden to the home infusion therapy AO associated with the review of the notice from CMS of changes to the CMS requirements would be $70.72 (1 hour x $35.36 per hour) + ($35.36 for fringe benefits and overhead). The estimated cost burden associated with the preparation and submission of the acknowledgement by the home infusion therapy AO would be $17.68 (15 minutes x $35.36 per hour = $8.84) + ($8.84 for fringe benefits and overhead). The estimates cost across the 6 potential home infusion therapy AOs would be $530.40 ($70.72 x 6 = $424.32) + ($17.68 x 6 = $106.08).

It is important to note that the home infusion therapy AOs would only have to perform these tasks if CMS were to make a change to the home infusion therapy standards. We believe that this would occur on an infrequent basis, therefore, the home infusion therapy AOs would incur these time and cost burdens on an infrequent basis.

Proposed § 488.1035(c) would require that the home infusion therapy AO permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

An example in which a surveyor would be needed to testify as a witness would be if there was litigation about CMS' termination of a home infusion therapy supplier's participation in the Medicare program and the surveyor that had performed a survey of that home infusion therapy supplier was needed to testify about the survey findings. The burden associated with this requirement would be the time the surveyor spent providing testimony, any travel expenses the home infusion therapy AO would be responsible to pay, and the wages paid to the surveyor during the time spent giving testimony.

The home infusion therapy AO would incur a time burden for the time required for the AO's surveyor to serve as a witness. This would include travel time to and from the location where the hearing is being held. The AO would also incur cost burdens for the wages paid to the surveyor during the time they are serving as a witness and also for any travel expenses the AO may be required to pay, that are not reimbursed.

It is important to note that the home infusion therapy AO surveyors would rarely, if ever, be required to act as a witness. Therefore, this is a burden that the home infusion therapy AOs would not be likely to incur.

Proposed § 488.1035(d) would require that, within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy AO must provide CMS with written notice of the deficiency and any adverse action implemented by the AO. The burden associated with this requirement is the time required to provide notice to CMS of the immediate jeopardy situation and the wages for the AO staff person for the time spent preparing and submitting this notice.

We believe that the AO would keep this information in the normal course of their

business of providing home infusion therapy accreditation. Therefore, the AO should have these readily available. We further believe that the home infusion therapy AOs would keep records related to immediate jeopardy findings in an electronic format.

The AO would incur a time burden for the time required to report the immediate jeopardy information to CMS. We estimate that it would take the AO no more than 20 minutes to prepare an email to CMS in which they provide the required information about the immediate jeopardy situation that has been discovered. The AO can attach electronic files to the email that contain the required information. It is important to note that we do not count, as a burden, the time spent by the home infusion therapy AO in finding the immediate jeopardy situation or resolving it, because it is the duty of any CMS-approved AO to monitor it's accredited providers or supplier to ensure they are providing care that meets the accreditation standards and that they do not have any situation that put the patients or general public in imminent danger of harm. The home infusion therapy AO would incur a cost burden for the wages of the AO staff that prepares the email to CMS which notified CMS of the immediate jeopardy situation. We believe that the person at the AO who would prepare the immediate jeopardy notification email to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation and submission of the acknowledgement by the home infusion therapy AO would be $23.60 ($35.36 divided by 60 minutes per hour = $0.59 per minute / 20 minutes x $0.59 per minute = $11.80) + ($11.80 for fringe benefits and overhead).

The home infusion therapy AOs would have to perform these tasks and incur these time

and costs burdens only if they discover an immediate jeopardy situation with an accredited home infusion therapy supplier. We would like to point out that this would not be a regular time and cost burden that would be incurred by the home infusion therapy AOs, as the discovery of immediate jeopardy situations by AOs do not occur frequently.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under §488.1035(d) across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to report an immediate jeopardy situation to CMS would only occur on a sporadic basis. We do not believe that there would ever be a situation in which all 6 potential AOs would be required to report an immediate jeopardy situation simultaneously. Proposed § 488.1035(e) would require that within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy AO that CMS intends to withdraw approval of the AO's home infusion therapy accreditation program, the home infusion therapy AO must provide written notice of the withdrawal to all of the home infusion therapy AO's accredited suppliers. The time burden associated with this requirement would be the time spent by the AO staff to prepare the required notice that must be sent to all of the AOs accredited home infusion therapy suppliers and the time required for the AO to send this notice out to all of its accredited suppliers.

We estimate that it would take that home infusion therapy AO approximately 45 minutes to prepare the notice that they must send out to their accredited suppliers. We believe it would take an additional 2 minutes per letter to be sent by the home infusion therapy AO to its accredited suppliers to prepare these letters for mailing (that is – fold letter, place in envelope, affix correct amount of postage and place the letter into the outgoing mail). We are not able to accurately estimate the amount of time it would take for the AO to send this notice

out to all of its accredited suppliers because this would be dependent on the number of accredited suppliers the AO has at the time. However, if were to assume that a home infusion therapy AO had 50 accredited home infusion therapy suppliers, this task would take the AO staff 1.7 hours to complete (2 minutes x 50 letters = 100 minutes / 100 minutes divided by 60 minutes per hour = 1.7 hours).

The home infusion therapy AO would incur a cost burden for the wages of the AO staff person that prepares the required notification. We believe that the person at the AO who would prepare the required notification would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be $53.04 (45 minutes x $35.36 per hour = $26.52) + ($26.52 for fringe benefits and overhead)

The home infusion therapy would also incur a cost burden for the wages of the staff person for the time spent preparing the required notices for mailing and mailing them. We are unable to accurately estimate this cost burden because the time required to perform this task would be dependent on the number of accredited home infusion therapy supplier the AO has at the time. However, if were to assume that a home infusion therapy AO had 50 accredited home infusion therapy suppliers, this task would take the AO staff 1.7 hours to complete (2 minutes x 50 letters = 100 minutes / 100 minutes divided by 60 minutes per hour = 1.7 hours). We believe that the person that would perform this task would be an Administrative Assistant. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for an executive administrative Assistant is $28.56 (https://www.bls.gov/oes/current/oes436011.htm).

Therefore, the home infusion therapy AO would incur a cost burden in the amount of $97.92 for the completion of this task ($28.56 per hour divided by 60 minutes per hour = $0.48 per minute / 60 minutes per hour divided by 10 = 6 minutes per 0.1 hour / 6 minutes x 7 = 42 minutes = 0.7 hour / 60 minutes + 42 minutes = 102 minutes or 1.7 hours / $0.48 per minute x 102 minutes = $48.96) + ($48.96 for fringe benefits and overhead).The home infusion therapy AO would incur an additional cost burden for miscellaneous costs. These costs would include the cost of the paper used to print the notices on, the printer ink used, the cost of the envelopes used, and the postage required to mail all the notices. We are unable to accurately estimate these costs as they are dependent on the number of notices that would be sent. We believe that these costs would not exceed $250.

It is important to note that the home infusion therapy AO surveyors would rarely, if ever, be required to perform the tasks required by proposed § 488.1035(e) because we would rarely withdraw the CMS approval of a home infusion therapy AO. We would do so if there were serious, unresolved compliance concerns that the AO was unable or unwilling to rectify, even after being placed on an accreditation program probationary period. We do not believe that it would be possible that all of the home infusion therapy AOs would incur these cost and time burdens at the same time.

(d) Burden for Home Infusion Therapy AOs Related to Proposed §488.1040

Proposed §488.1040 would require that as part of the application review process, the ongoing review process, or the continuing oversight of an home infusion therapy AO's performance, CMS may conduct onsite inspections of the home infusion therapy AO's operations and offices at any time to verify the home infusion therapy AO's representations and to assess the home infusion therapy AO's compliance with its own policies and procedures.

Proposed §488.1040(b) provides that the activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following: (1) interviews with various AO staff; (2) review of documents, survey files, audit tools, and related records; (3) observation of meetings concerning the home infusion therapy accreditation process; (4) auditing meetings concerning the accreditation process; (5) observation of in-progress surveys and audits; and (6) evaluation of the AO's survey results and accreditation decision-making process.

We believe that there would be little burden associated with the onsite visits made by CMS to the home infusion therapy AO's operations and offices because most of the activities related to the onsite visit involve work performed by the CMS staff, which would not impose burden on the AO staff (such as review of records or observation of meeting held at the AOs offices). We estimate that the time burden to the home infusion therapy AO associated with these onsite visits would include the time required for the AO staff to greet the CMS team upon arrival and show them to the conference room, the time required to locate the records the CMS team requests for review, and the time required for CMS to conduct interviews of AO staff members. If the home infusion therapy AOs records are electronic, an AO staff member may need to remain with the CMS team during their record review to assist them with access to the AO's records.

We are not able to accurately estimate the total time that would be required for these activities because we have not yet accredited any home infusion therapy AOs, nor have we had an opportunity to perform an onsite visit to a home infusion therapy AO. We do not yet know what type of accreditation standards and surveys processes the home infusion therapy AOs would use. Also, we do not know the amount and type of records we would seek to review during an onsite visit to a home infusion therapy AO or approximately how much time we

would need to review these records. Likewise, we do not yet know how much interaction we would need to have with the home infusion therapy AO staff or which AO staff members we would choose to interview. The onsite AO visits we have performed for other types of AOs have lasted 1 to 2 days depending on the type of AO.

However, if we estimate that it would take 1 hour for the CMS team entrance conference, 8 hours for the CMS team to perform their records review and 1 hour for the CMS team conduct the exit conference, the home infusion therapy AO would incur a time burden in the amount of 1 hour for each AO staff person that attends the entrance conference, 8 hours for any staff that remains with the CMS team to assist them with the record review and 1 hour of time for each AO staff person that attends the exit conference. We believe that the AO staff that would be attending the entrance and exit conferences and assisting the CMS staff with their records review would most likely be clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a non-industry specific registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). We estimate that approximately 4 AO staff persons would attend the entrance and exit conferences and that one AO staff person would assist the CMS team with their record review.

Based on the a previously stated time estimate, we estimate that the home infusion therapy AO would incur a cost burden in the amount of $282.88 for wages for four AO staff for attendance at the entrance conference. ($35.36 per hour per each AO staff x 1 hour = $35.36 / $35.36 per hour x 4 AO staff = $141.44) + ($141.44 for fringe benefits and overhead).

We further estimate that the AO would incur a cost burden in the amount of $282.88 for the wages of the four AO staff for attendance at the exit conference. ($35.36 per hour per each AO staff x 1 hour = $35.36 / $35.36 per hour x 4 AO staff = $141.44) + ($141.44 for fringe

benefits and overhead).

We also estimate that the AO would incur a cost burden in the amount of $565.76 for the wages of the AO staff person that would remain with the CMS team to assist them with their record review. (8 hours x $35.36 = $282.88) + ($282.88 for fringe benefits and overhead).

The total estimated cost burden to the home infusion therapy AO associated with the CMS onsite visit is $1,131.52 ($282.88 for entrance conference + $282.88 for exit conference + $565.76 for assisting CMS staff with record review = $1,131.52). The estimated cost burden across all of the potential six home infusion therapy AOs would be $6,789.12.

In this proposed rule, we have proposed that the six AOs that currently provide accreditation to home infusion therapy suppliers must submit an application to CMS for approval of a separate and distinct home infusion therapy accreditation program. A corporate onsite visit to the home infusion therapy AOs office is a part of the application review and approval process. Therefore, each of the AOs that submit an application to CMS for approval of a home infusion therapy program would incur the previously stated estimated burden related to the corporate onsite visit. However, after the initial application process has been completed, CMS would only make additional corporate onsite visits every 6 years when the home infusion therapy AOs submit their renewal application. Therefore, this would not be is a frequent or ongoing burden incurred by the home infusion therapy AOs.

(e) Burden for Home Infusion Therapy AOs Related to Proposed §488.1045

Proposed §488.1045 contains regulations related to the voluntary and involuntary termination of the CMS approval of a home infusion therapy AO's home infusion therapy accreditation program. Proposed §488.1045(a) would provide that a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion

therapy accreditation program must provide written notice at least 90 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

The requirement that the home infusion therapy AO provide notice of its decision to voluntarily terminate its CMS approved home infusion therapy accreditation program to CMS and all of its accredited home infusion therapy suppliers would cause the AO to incur the following time burdens: (1) the time required to prepare and send the required notice to CMS; and (2) the time required to prepare and send the required notice to all of the AOs accredited home infusion therapy suppliers. We would require that the AO send the required notice of their decision to voluntarily terminate its CMS-approved accreditation program to CMS by U.S. mail. We would also require the AO to send the required notice to all of its accredited home infusion therapy suppliers by U.S. mail. We estimate that it would take approximately 60 minutes for the AO staff person to prepare the letter to CMS in which the AO notified CMS that the AO wishes to voluntarily terminate its CMS-approved home infusion therapy accreditation program, print the letter and mail it.

We further estimate that it would take the AO staff person another 4 hours to perform the following tasks: (1) draft a letter its accredited home infusion therapy suppliers, giving notice that the AO is voluntarily terminating its CMS approved home infusion therapy accreditation program; (2) perform a mail merge to prepare a copy of the letter addressed to each accredited home infusion therapy supplier; (3) print out a letter to each accredited supplier and envelope; put the letters into the envelopes; (4) affix the correct amount of postage; and (5) put the envelopes in the outgoing mail. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse.

According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be $35.36 (60 minutes x $35.36 per hour = $35.36).

The home infusion therapy AO would also incur a cost burden for the wages of the staff person for the time spent preparing and mailing the required notices to be sent to the AO's accredited home infusion therapy suppliers. As stated previously, we estimate that it would take approximately 4 hours of time for an AO staff person to prepare the required notification letter to the AOs accredited providers, print out a copy of the letter for each accredited home infusion therapy supplier and put these letters into the mail. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice for mailing would be $353.60 (4 hours x $35.36 per hour = $176.80) + ($176.80 for fringe benefits and overhead).

The home infusion therapy AO would incur an additional burden for miscellaneous costs associated with the preparation of the required notices to be sent to CMS and the AOs accredited home infusion therapy suppliers, including the cost of the paper on which the notices are printed, the printer ink used, the cost of the envelopes used, and the postage required to mail all of the notices. We are unable to accurately estimate these costs as they are dependent on the number of notices that would need to be sent. However we believe these costs would not

exceed $200. We seek comment on how to estimate this burden.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under §488.1045 across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks only arise if a home infusion therapy AO voluntarily decides to terminate its CMS approved home infusion therapy accreditation program. This would occur rarely, if ever.

We do not believe that there would ever be a situation in which all six of the potential home infusion therapy AOs would decide to terminate their CMS approved accreditation programs simultaneously.

Proposed §488.1045(b) states that once CMS publishes a notice in the **Federal Register** announcing the decision to involuntarily terminate the home infusion therapy AO's home infusion therapy accreditation program, the home infusion therapy AO must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program by no later than 30 calendar days after the notice is published in the **Federal Register.** This notice would announce that CMS is withdrawing its approval of the AOs home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at §488.1010(f) once their current term of accreditation expires.

The time burden associated with proposed §488.1045(b) would be the time it takes for the home infusion therapy AO to prepare and send the required written notification to all accredited home infusion therapy suppliers which states that CMS is withdrawing the AOs approval of the home infusion therapy accreditation program and which also states the

implications for the home infusion therapy suppliers payment status. We estimate that it would take no more than 4 hours for an AO staff person to perform the following tasks: (1) draft the required notification letter; (2) perform a mail merge to prepare a copy of the letter that is addressed to each home infusion therapy supplier accredited by the AO; (3) print copies of the notification letters for each of the AOs accredited home infusion therapy suppliers; (4) put each notifications letter into an envelope; (5) affix the correct amount of postage to the envelope and (6) put the envelopes into the outgoing mail.

The home infusion therapy AO would incur a cost burden for the wages for the AO staff who performs the previously stated tasks. We believe that the person at the AO who would perform these tasks would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required notice which is to be sent to all of the AO's accredited suppliers would be $282.88 (4 hours x $35.36 per hour = $141.44) + ($141.44 for fringe benefits and overhead).

The home infusion therapy AO would incur an additional burden for miscellaneous costs associated with the preparation of the required notices to be sent to the AOs accredited home infusion therapy suppliers, including the cost of the paper on which the notices are printed, the printer ink used, the cost of the envelopes used, and the postage required to mail all of the notices. We believe that these costs would not exceed $200.

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under §488.1045 across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO

to perform these tasks required by §488.1045(b) would only arise if CMS decides to involuntarily terminate the CMS approval of the AO's home infusion therapy accreditation program. This would occur rarely, if ever. Also, we do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would decide to terminate their CMS approved accreditation programs simultaneously.

Proposed §488.1045(c)(3) would require that for both voluntary and involuntary terminations of a home infusion therapy AOs CMS approved home infusion therapy accreditation program, the home infusion therapy AO must provide a second written notification to all of its accredited home infusion therapy suppliers ten calendar days prior to the AO's accreditation program termination effective date. We estimate that the time and cost burdens associated with this requirement would be the same as our estimated burden for proposed §488.1045(b) set forth previously.

Proposed §488.1045(d) sets forth the required steps that a home infusion therapy AO must take when one of its accredited home infusion therapy suppliers has requested a voluntary withdrawal from accreditation. The withdrawal from accreditation by the home infusion therapy supplier may not become effective until the AO completes all of the following 3 steps: (1) the home infusion therapy AO must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program; (2) the home infusion therapy AO must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status; (3) the home infusion therapy AO must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to

CMS by no later than 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

The burden associated with the requirement that the home infusion therapy AO contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program would include the time required for the AO to contact the home infusion therapy supplier to request written confirmation that the home infusion therapy supplier does indeed want to terminate their home infusion therapy accreditation. We estimate that the AO would most likely contact the home infusion therapy supplier to make this request by telephone or email. We estimate this would take no more than 15 minutes.

The AO would incur a cost burden for the wages of the AO staff person for the time spent contacting the home infusion therapy supplier to confirm they intend to voluntarily withdraw from the home infusion therapy accreditation program. We believe that the person at the AO who would perform this task would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with contacting the home infusion therapy supplier to confirm that they do want to voluntarily terminate would be $17.68 (15 minutes x $35.36 per hour = $8.84) + ($8.84 for fringe benefits and overhead).

The home infusion therapy AO would also incur a time burden associated with the requirement that they send a written notice to the home infusion therapy supplier that is voluntarily terminating their home infusion therapy accreditation, which provides notice of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible

payment consequences for a lapse in accreditation status. We estimate that it would take the home infusion therapy no more than 60 minutes to prepare the written notification.

We believe that the person at the AO who would prepare the required written notice to be sent to the home infusion therapy supplier that is voluntarily terminating its home infusion therapy accreditation would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the required written notice would be $70.72 (1 hours x $35.36 per hour = $35.36) + ($35.36 for fringe benefits and overhead). We further estimate that the AO would incur postage costs in the amount of $0.50 for each letter sent.

Finally, we estimate the burden associated with §488.1045(d)(3) would include the time required for the home infusion therapy AO staff to prepare a final notice of voluntary withdrawal of accreditation by the home infusion therapy supplier and the time required to send this notice to CMS. We estimate that it would only take the AO staff 15 minutes or less to prepare the required notice for CMS, because this notice could be sent to CMS by email. We estimate it would take an additional 10 minutes of time for the AO staff to prepare the email and attach the written notice to the email.

The AO would incur a cost burden for the wages of the AO staff for the time spent preparing the notice and sending it to CMS. We believe that the person at the AO who would prepare the required written notice to be sent to CMS would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the

estimated cost burden to the home infusion therapy AO associated with the preparation of the required written notice to be sent to CMS would be $29.48 (15 minutes x $35.36 per hour = $8.84) + (10 minutes x $35.36 per hour = $5.90) +($14.74 for fringe benefits and overhead).

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under §488.1045(d) across all of the potential home infusion therapy AOs. We have not done so because the need for a home infusion therapy AO to perform these tasks would only arise if a home infusion therapy supplier would decide to voluntarily terminate its accreditation with the home infusion therapy AO. This would occur on an infrequent basis. We do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would have a home infusion therapy supplier decide to voluntarily terminate the accreditation with their home infusion therapy AOs simultaneously.

(f) Burden for Home Infusion Therapy AOs Associated with Proposed §488.1050

Proposed §488.1050(a) would provide that a home infusion therapy AO that is dissatisfied with a determination, made by CMS, that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy AO meet the applicable quality standards is entitled to reconsideration.

Proposed §488.1050(b)(1) would require that a written request for reconsideration be filed within 30 calendar days of the receipt of CMS' notice of an adverse determination or non-renewal. Proposed §488.1050(b)(2) would provide that the written request for reconsideration must specify the findings or issues with which the home infusion therapy AO disagrees and the reasons for the disagreement. Proposed §488.1050(c)(1) provides the opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and proposed

§488.1050(c)(2) provides that written notice of the time and place of the hearing will be provided at least 10 business days before the scheduled date.

We estimate that it would take approximately 2 hours for a home infusion therapy AO to prepare its request for reconsideration. We believe that the person at the AO who would prepare the request for reconsideration would most likely be a clinician such as a registered nurse. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the home infusion therapy AO associated with the preparation of the request for reconsideration would be $141.44 (2 hours x $35.36 per hour = $70.72) + ($70.72 for fringe benefits and overhead).

The remaining information that would be submitted in connection with a request for reconsideration or a reconsideration hearing, including any evidence or testimony provided is not considered "information" in accordance with 5 CFR 1320.3(h)(8), which excludes as "information" any "facts or opinions obtained or solicited at or in connection with public hearings."

It is important to note that we have not calculated the burden associated with the tasks required of the home infusion therapy AO under §488.1050 across all of the potential home infusion therapy AOs. We have not done so because we believe that the filing of a request for reconsideration by a home infusion therapy AO would occur rarely, if ever. Further, we do not believe that there would ever be a situation in which all 6 of the potential home infusion therapy AOs would decide to file a request for reconsideration at the same time. Therefore, there would never be an occurrence where all the home infusion therapy AOs would incur the previously stated burden simultaneously.

(g) Burdens for Home Infusion Therapy AOs Related to Survey Activities and Accreditation of Home Infusion Therapy Suppliers

The home infusion therapy AO would incur time and cost associated the accreditation of home infusion therapy suppliers. These would include the time and costs required to perform an onsite survey, offsite survey or other type of survey activity for each home infusion therapy supplier that has hired that AO to provide accreditation. However, as we have not approved any home infusion therapy AOs, we do not yet know what type of home infusion therapy accreditation standards they will use, or what the home infusion therapy accreditation survey process will consist of. Therefore, we are unable to accurately estimate the time and cost burden associated with the survey of home infusion therapy suppliers.

However, we can state that if the home infusion therapy AO were to perform an onsite survey, it would incur wages for each of the surveyors that are sent to perform the survey for the amount of time spent performing the survey. The AO would also incur wages for the time spent by the surveyors or other home infusion therapy AO staff in reviewing the survey documents, making a decision about whether to grant accreditation to the home infusion therapy supplier that was surveyed and preparing the decision letter to the home infusion therapy supplier. The AO would also incur travel costs for the AO staff to travel to the home infusion therapy supplier's location to perform the survey.

If the home infusion therapy AO were to do an offsite records audit survey, the AO would request that the home infusion therapy supply the AO with specific records. The AO would incur costs for the wages of the AO staff that performed the audit of the documents provided by the home infusion therapy supplier. The AO would also incur wages for the time spent by the surveyors or other home infusion therapy AO staff in making a decision about

whether to grant accreditation to the home infusion therapy supplier that was audited and preparing the decision letter to the home infusion therapy supplier.

We seek comment on how to estimate this burden.

2. Burden to Home Infusion Therapy Suppliers Related to Home Infusion Therapy Health and Safety Standards

All existing home infusion therapy suppliers are already accredited by existing home infusion therapy AOs to meet requirements established by private insurers and Medicare Advantage plans. We are proposing that, in order for the existing home infusion therapy suppliers accredited by these AOs to continue to receive payment for the home infusion therapy services provided, these AOs must obtain Medicare approval for a home infusion therapy accreditation program. To obtain this CMS approval, we are proposing that these AOs would be required to submit an application to CMS seeking approval of a home infusion therapy accreditation program that meets the requirements set forth in the proposed new home infusion therapy AO approval and oversight regulations and proposed new home infusion therapy health and safety regulations. We would also require that the home infusion therapy program submitted by these AOs be separate and distinct from the AOs home health deeming accreditation program.

It is likely that the home infusion therapy suppliers would need to be resurveyed after their home infusion therapy AO obtains CMS approval of a home infusion therapy accreditation program, under section 1861(iii)(3)(D)(i)(III) of the Act. We believe this resurvey would be necessary because the AOs would have to determine if the home infusion therapy suppliers they accredit meet their new Medicare-approved home infusion therapy accreditation program accreditation standards. However, if a current home infusion therapy AOs current home

infusion therapy standards already meet or exceed the proposed home infusion therapy health and safety standards, so that a revision of that AOs home infusion therapy accreditation standards is not required, then a resurvey of that AO's accredited home infusion therapy suppliers may not be necessary.

The home infusion therapy supplier would incur some time burden in order to come into compliance with the home infusion therapy AOs new home infusion therapy accreditation program requirements initially and thus prepare for the accreditation survey. However, all existing home infusion therapy suppliers are already accredited by existing home infusion therapy AOs to meet requirements established by private insurers and Medicare Advantage plans. Therefore, we assume that there would be little, is any new burden imposed on home infusion therapy suppliers in order to implement the proposed new health and safety standards.

The home infusion therapy supplier would be charged a fee by the AO for providing accreditation services. Fees for the home infusion therapy accreditation currently offered by the six AOs listed previously accreditation programs offered by the six AOs listed previously vary between $5,950 and $12,500 and, in general, currently cover all of the following items: application fee, manuals, initial accreditation fee, onsite surveys or other auditing (generally once every 3 years), and travel, when necessary for survey personnel. Accreditation costs also vary by the size of the provider or supplier seeking accreditation, its number of locations, and the number of services it provides.

We recognize that cost and time burdens associated with becoming accredited may be a barrier for small suppliers such as home infusion therapy suppliers. We propose to implement the following to minimize the burden of accreditation on suppliers, including small businesses:

- Multiple accreditation organizations--We expect that more than one AO would

submit an application to become a designated Home Infusion Therapy AO. We believe that selection of more than one home infusion therapy AO would introduce competition resulting in reductions in accreditation costs.

- Required plan for small businesses--During the application process we would require prospective home infusion therapy AOs to include a plan that details their methodology to reduce accreditation fees and burden for small or specialty suppliers. This would need to include that the AO's fees are based on the size of the organization.

- Reasonable quality standards--The quality standards that would be used to evaluate the services rendered by each home infusion therapy supplier are being proposed in this rule. Many home infusion therapy suppliers already comply with the standards and have incorporated these practices into their daily operations. It is our belief that compliance with the quality standards would result in more efficient and effective business practices and would assist suppliers in reducing overall costs.

There are at least two important sources of uncertainty in estimating the impact of accreditation on home infusion therapy suppliers. First, our estimates assume that all home infusion therapy suppliers with positive Medicare payments would seek accreditation. We assume that home infusion therapy suppliers who currently receive no Medicare allowed charges would choose not to seek accreditation. It is also possible that many of the home infusion therapy suppliers with allowed charges between $1 and $1,000 may decide not to incur the costs of accreditation.

Second, it is difficult to predict what accreditation fees would be in the future. Our experience with other accreditation programs has lead us to believe that the accreditation rates would go up, due to factors such as wage increases, and increased travel costs. To monitor

accreditation fees, we propose to require the AOs for home infusion therapy suppliers to submit their proposed fees to CMS for review for reasonableness. We would require home infusion therapy AOs to notify CMS anytime there is an increase in accreditation fees.

(d) Medicare-certified Accreditation Organizations--Proposed Changes to 42 CFR 488.5

We have proposed to modify the AO approval and oversight regulations for Medicare-certified providers and suppliers by adding two new requirements. The first proposed new requirement is to added to 42 CFR 488.5(a)(7) and is a requirement that in their application for CMS approval, the AOs that accredited Medicare-certified providers and suppliers must include a statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter. The second requirement is to be added as §488.5(a)(18)(iii) and would require that the AOs for Medicare-certified providers and suppliers include a written statement in their application for CMS approval agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

(1) Burden Associated with the Online Training Requirement for AO Surveyors

CMS provides a number of online surveyor training modules that are available to the State Survey Agency surveyors. We have proposed to require the AO surveyors to take this training in an attempt to decrease the historically high disparity rate between the AOs survey results and those of the validation surveys performed by the State Survey Agency surveyors.

CMS offers 168 online surveyor training programs that are available for the State Survey Agency surveyors. This website provides courses that are general in nature such as "Principles of Documentation Learning Activity – Long Term Care", "Basic Writing Skills for Surveyor Staff", Infection Control, Patient Safety, and Emergency Preparedness. The CMS Surveyor Training website also offers courses related to specific healthcare settings, services, and regulations, such as hospitals, CAHs, ASCs, CLIA, CMHCs, EMTALA, FQHCs, HHAs and OASIS, Hospices, Nursing Homes and the MDS, Outpatient Physical Therapy/Outpatient Speech Therapy (OPT/OST). These courses are self-paced and the person taking the course can take the courses over a period of time. The amount of time required to complete each of these training course varies depending on the pace preferred by the trainee.

We estimate that each SA surveyor takes approximately 10 courses on the CMS Surveyor Training website. We estimate that it would take approximately 3-5 hours to complete each of these courses. We believe that the surveyors for AOs that accredit Medicare-certified providers should take the same number and type of surveyor training courses as the SA surveyors (that is - approximately 10 courses). This means that each of the AOs surveyors that takes this training would incur a time burden in the amount of 30 to 50 hours.

The AOs that accredit Medicare-certified providers and suppliers would incur a cost burden for the wages of the surveyor for the time they spend taking these online surveyor training courses. Most surveyors are clinicians such as registered nurses. According to the U.S. Bureau of Labor Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). As noted previously, we estimated that it would take approximately 30-50 hours for each AO surveyor to complete 10 online surveyor courses. Therefore, the AO would incur wages in the amount of $1,060.80 to $1,768 per each

surveyor that completes the CMS online surveyor training (($35.36 x 30 hours = $1,060.80) and ($35.36 x 50 hours = $1,768)). The AO would also incur additional costs for fringe benefits and overhead in the amount of $1,060.80 to $1,768.00 per each surveyor that completes the CMS online surveyor training.

We are not able to accurately estimate to total time and cost burden to each AO for the wages incurred for the time spent by all surveyors of that AO that take the CMS online surveyor training courses, because we do not know exactly how many surveyors each AO has. However, if we estimate that each AO has 15 surveyors, the estimated time burden to each AO associated with this requirement would be 450 to 750 hours ((30 hours x 15 surveyors = 450 hours per all surveyors) and (50 hours x 15 surveyors = 750 hours per all surveyors)). The estimated cost burden to each AO for Medicare-certified providers and supplies associated with this requirement would be $31,824 to $53,040 (($1,060.80 x 15 = $15,912) and ($1,768.00 x 15= $26,520) and ($15,912 to $26,520 for fringe benefits and overhead)).

There are currently 9 AOs that accredit Medicare-certified providers and suppliers. We estimate that the time burden across all of these AOs associated with the requirement that their surveyors take the CMS online surveyor training would be 4,050 to 6,750 ((450 hours per all surveyors/AO x 9 AOs = 4,050 hours across all AOs) and (750 hours per all surveyors/AO x 9 AOs = 6,750 hours across all AOs). The estimated cost across all AOs that accredit Medicare-certified providers and suppliers would be $143,208 to $238,680 (($15,912 x 9 AOs = $143,208) and ($26,520 x 9 AOs = $238,680)). The cost for fringe benefits and overhead on these estimated wages across all AOs would be $143,208 to 238,680.

(2) Burden Associated with the Statement Requirement for AOs

We are proposing that AOs approved in accordance with section 1865 of the Act, and

regulated under part 488 subpart A, provide a written statement in their application in which they agree to continue a provider's or supplier's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

Proposed §488.5(a)(18)(iii) would require the AOs for Medicare-certified providers and suppliers to include a written statement in their application for CMS approval of their accreditation program, agreeing that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

We believe that the AOs that accredit Medicare-certified providers and suppliers would incur limited burden associated with this requirement, because this proposed regulation simply requires that the AOs to include a statement in their application stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program. We believe that this written statement to be provided by the AO would consist of only 1 to 2 paragraphs and would take no more than 15 minutes to prepare.

We believe that a clinicians such as registered nurses would prepare the required statement to be included in the AOs application. According to the U.S. Bureau of Labor

Statistics, the mean hourly wage for a registered nurse is $35.36 (https://www.bls.gov/oes/current/oes291141.htm). Therefore, the estimated cost burden to the AOs that accredit Medicare-certified providers and suppliers associated with the preparation of the required statement would be approximately $17.68 ((15 minutes x $35.36 per hour = $8.84) + ($8.84 for fringe benefits and overhead)).

There are nine AOs that accredit Medicare-certified providers and suppliers. The cost across all AOs for the completion of this task would be $158.12 (($8.84 x 9 AOs = $79.56) + ($79.56 for fringe benefits and overhead. However, AOs for Medicare-certified providers and suppliers are required to submit a renewal application only every six years. Therefore, the existing AOs would be required to submit the statement stating that they agree to continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first, if a provider of supplier provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program with their next renewal application which is submitted after the publication of the final rule. While we have calculated the cost for the performance of this task across all AOs that accredit Medicare-certified providers and suppliers, it is important to note that the existing AOs are scheduled to submit their renewal applications at varying dates and times over a period of several years. Therefore there will be no time period in which all of these AOs will incur these expenses simultaneously.

D. Detailed Economic Analysis

1. HH PPS

This rule proposes updates for the CY 2019 HH PPS rates contained in the CY 2018 HH

PPS final rule (82 FR 51676 through 51752). The impact analysis of this proposed rule presents the estimated expenditure effects of policy changes proposed in this rule. We use the latest data and best analysis available, but we do not make adjustments for future changes in such variables as number of visits or case-mix.

This analysis incorporates the latest estimates of growth in service use and payments under the Medicare HH benefit, based primarily on Medicare claims data from 2017. We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to errors resulting from other changes in the impact time period assessed. Some examples of such possible events are newly-legislated general Medicare program funding changes made by the Congress, or changes specifically related to HHAs. In addition, changes to the Medicare program may continue to be made as a result of the Affordable Care Act, or new statutory provisions. Although these changes may not be specific to the HH PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon HHAs.

a. HH PPS for CY 2019

Table 59 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2019. For this analysis, we used an analytic file with linked CY 2017 OASIS assessments and HH claims data for dates of service that ended on or before December 31, 2017. The first column of Table 59 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of facilities in the impact analysis. The third column shows the payment effects of the CY 2019 wage index and revised labor share. The fourth column

shows the payment effects of the CY 2019 case-mix weights. The fifth column shows the effects of the new rural add-on payment provision in statute. The sixth column shows the effects of the revised FDL ratio used to calculate outlier payments, and the seventh column shows the effects of the CY 2019 home health payment update percentage.

The last column shows the combined effects of all the policies proposed in this rule. Overall, it is projected that aggregate payments in CY 2019 would increase by 2.1 percent. As illustrated in Table 59, the combined effects of all of the changes vary by specific types of providers and by location. We note that some individual HHAs within the same group may experience different impacts on payments than others due to the distributional impact of the CY 2019 wage index, the extent to which HHAs had episodes in case-mix groups where the case-mix weight decreased for CY 2019 relative to CY 2018, the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, and the degree of Medicare utilization.

TABLE 59: ESTIMATED HHA IMPACTS BY FACILITY TYPE AND AREA OF THE COUNTRY, CY 2019

	Number of Agencies	CY 2019 Wage Index and Labor Share[1]	CY 2019 Case-Mix Weights[2]	Rural Add-On Revisions	Updated Outlier FDL Ratio 0.51	CY 2019 HH Payment Update Percentage[3]	Total
All Agencies	10,547	0.0%	0.0%	-0.1%	0.1%	2.1%	2.1%
Facility Type and Control							
Free-Standing/Other Vol/NP	1,065	-0.3%	-0.1%	0.0%	0.2%	2.1%	1.9%
Free-Standing/Other Proprietary	8,366	0.1%	0.0%	-0.1%	0.1%	2.1%	2.2%
Free-Standing/Other Government	260	0.3%	0.1%	-0.1%	0.2%	2.1%	2.6%
Facility-Based Vol/NP	604	0.0%	0.0%	0.0%	0.2%	2.1%	2.3%
Facility-Based Proprietary	76	-0.3%	0.1%	-0.2%	0.2%	2.1%	1.9%
Facility-Based Government	176	-0.1%	0.0%	-0.3%	0.2%	2.1%	1.9%
Subtotal: Freestanding	9,691	0.0%	0.0%	-0.1%	0.1%	2.1%	2.1%
Subtotal: Facility-based	856	-0.1%	0.0%	-0.1%	0.2%	2.1%	2.1%

	Number of Agencies	CY 2019 Wage Index and Labor Share[1]	CY 2019 Case-Mix Weights[2]	Rural Add-On Revisions	Updated Outlier FDL Ratio 0.51	CY 2019 HH Payment Update Percent-age[3]	Total
Subtotal: Vol/NP	1,669	-0.2%	-0.1%	0.0%	0.2%	2.1%	2.0%
Subtotal: Proprietary	8,442	0.1%	0.0%	-0.1%	0.1%	2.1%	2.2%
Subtotal: Government	436	0.1%	0.0%	-0.2%	0.2%	2.1%	2.2%
Facility Type and Control: Rural							
Free-Standing/Other Vol/NP	253	0.1%	0.1%	-0.3%	0.2%	2.1%	2.2%
Free-Standing/Other Proprietary	821	0.6%	0.0%	-0.7%	0.1%	2.1%	2.1%
Free-Standing/Other Government	176	0.5%	0.1%	-0.2%	0.2%	2.1%	2.7%
Facility-Based Vol/NP	273	0.2%	0.1%	-0.3%	0.2%	2.1%	2.3%
Facility-Based Proprietary	41	0.1%	0.2%	-0.5%	0.1%	2.1%	2.0%
Facility-Based Government	134	0.2%	0.1%	-0.4%	0.2%	2.1%	2.2%
Facility Type and Control: Urban							
Free-Standing/Other Vol/NP	812	-0.4%	-0.1%	0.0%	0.2%	2.1%	1.8%
Free-Standing/Other Proprietary	7,545	0.0%	0.0%	0.0%	0.1%	2.1%	2.2%
Free-Standing/Other Government	84	0.1%	0.1%	0.0%	0.2%	2.1%	2.5%
Facility-Based Vol/NP	331	-0.1%	-0.1%	0.0%	0.2%	2.1%	2.1%
Facility-Based Proprietary	35	-0.6%	0.1%	0.0%	0.2%	2.1%	1.8%
Facility-Based Government	42	-0.4%	-0.1%	-0.1%	0.1%	2.1%	1.6%
Facility Location: Urban or Rural							
Rural	1,698	0.4%	0.0%	-0.6%	0.1%	2.1%	2.0%
Urban	8,849	0.0%	0.0%	0.0%	0.1%	2.1%	2.2%
Facility Location: Region of the Country (Census Region)							
New England	363	-0.9%	0.0%	0.0%	0.2%	2.1%	1.4%
Mid Atlantic	482	-0.3%	-0.2%	0.0%	0.2%	2.1%	1.8%
East North Central	2,031	-0.3%	0.1%	0.0%	0.1%	2.1%	2.0%
West North Central	705	0.0%	0.1%	0.0%	0.2%	2.1%	2.4%
South Atlantic	1,647	0.0%	-0.2%	0.0%	0.1%	2.1%	2.0%
East South Central	423	0.1%	-0.1%	-0.5%	0.1%	2.1%	1.7%
West South Central	2,774	0.6%	0.1%	-0.3%	0.1%	2.1%	2.6%
Mountain	678	-0.3%	0.1%	0.1%	0.2%	2.1%	2.2%
Pacific	1,403	0.3%	0.2%	0.0%	0.1%	2.1%	2.7%
Other	41	0.9%	-0.9%	0.0%	0.2%	2.1%	2.3%
Facility Size (Number of First Episodes)							
< 100 episodes	2,907	0.0%	0.3%	0.0%	0.2%	2.1%	2.6%
100 to 249	2,301	0.1%	0.4%	-0.1%	0.1%	2.1%	2.6%
250 to 499	2,218	0.1%	0.3%	-0.1%	0.1%	2.1%	2.5%

	Number of Agencies	CY 2019 Wage Index and Labor Share[1]	CY 2019 Case-Mix Weights[2]	Rural Add-On Revisions	Updated Outlier FDL Ratio 0.51	CY 2019 HH Payment Update Percent-age[3]	Total
500 to 999	1,637	0.1%	0.1%	-0.1%	0.1%	2.1%	2.3%
1,000 or More	1,484	0.0%	-0.1%	-0.1%	0.1%	2.1%	2.0%

Source: CY 2017 Medicare claims data for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.
[1] The impact of the CY 2019 home health wage index is offset by the wage index budget neutrality factor described in section III.C.4 of this proposed rule.
[2] The impact of the CY 2019 home health case-mix weights reflects the recalibration of the case-mix weights offset by the case-mix weights budget neutrality factor described in section III.B of this proposed rule.
[3] The CY 2019 home health payment update percentage reflects the home health payment update of 2.1 percent as described in section III.C.2 of this proposed rule.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York;
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
P**acific**=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

b. HH PPS for CY 2020 (Proposed PDGM)

Table 60 represents how HHA revenues are likely to be affected by the policy changes proposed in this rule for CY 2020. For this analysis, we used an analytic file with linked CY 2017 OASIS assessments and CY 2017 HH claims data (as of March 2, 2018) for dates of service that ended on or before December 31, 2017. The first column of Table 60 classifies HHAs according to a number of characteristics including provider type, geographic region, and urban and rural locations. The second column shows the number of HHAs in the impact analysis. The PDGM, as required by Section 51001(a)(2)(A) of the BBA of 2018, will be implemented in a budget neutral manner and the third column shows the total impact of the proposed PDGM as outlined in section III.F of this proposed rule. As illustrated in Table 60,

the effect of the proposed PDGM varies by specific types of providers and location. We note that some individual HHAs within the same group may experience different impacts on payments than others. This is due to distributional differences among HHAs with regards to the percentage of total HH PPS payments that were subject to the low-utilization payment adjustment (LUPA) or paid as outlier payments, the degree of Medicare utilization, and the ratio of overall visits that were provided as therapy versus skilled nursing.

As outlined in section III.F of this proposed rule, several OASIS items would no longer be needed to case-mix adjust the 30-day payment under the PDGM; therefore, we would make 19 current OASIS items (48 data elements) optional at the FU time point starting January 1, 2020. As also discussed in section III.F. of this proposed rule, in order to calculate the case-mix adjusted payment amount for the PDGM, we would add the collection of two current OASIS items (10 data elements) at the FU time point starting January 1, 2020. Section VII of this proposed rule provides a detailed description of the net decrease in burden associated with these proposed changes in conjunction with the changes in burden that result from OASIS item collection changes due to the proposed removal of certain measures required under HH QRP, also effective for January 1, 2020 as outlined in section V.E of this rule. We estimate that the burden associated with OASIS item collection as a result of this proposed rule results in a net $60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

TABLE 60: IMPACTS OF PDGM, CY 2020

	Number of Agencies	PDGM
All Agencies	**10,480**	**0.0%**
Facility Type and Control		
Free-Standing/Other Vol/NP	1,055	2.6%
Free-Standing/Other Proprietary	8,309	-1.2%
Free-Standing/Other Government	260	1.1%

	Number of Agencies	PDGM
Facility-Based Vol/NP	604	3.8%
Facility-Based Proprietary	76	4.4%
Facility-Based Government	176	4.6%
Subtotal: Freestanding	9,624	-0.4%
Subtotal: Facility-based	856	3.9%
Subtotal: Vol/NP	1,659	2.9%
Subtotal: Proprietary	8,385	-1.2%
Subtotal: Government	436	2.9%
Facility Type and Control: Rural		
Free-Standing/Other Vol/NP	253	3.8%
Free-Standing/Other Proprietary	820	3.9%
Free-Standing/Other Government	176	1.9%
Facility-Based Vol/NP	273	4.1%
Facility-Based Proprietary	41	11.3%
Facility-Based Government	134	5.9%
Facility Type and Control: Urban		
Free-Standing/Other Vol/NP	802	2.4%
Free-Standing/Other Proprietary	7,489	-1.8%
Free-Standing/Other Government	84	0.3%
Facility-Based Vol/NP	331	3.7%
Facility-Based Proprietary	35	0.1%
Facility-Based Government	42	3.4%
Facility Location: Urban or Rural		
Rural	1,697	4.0%
Urban	8,783	-0.6%
Facility Location: Region of the Country (Census Region)		
New England	354	2.5%
Mid Atlantic	479	3.1%
East North Central	2,012	-1.1%
West North Central	703	-3.9%
South Atlantic	1,643	-5.3%
East South Central	423	0.9%
West South Central	2,750	4.1%
Mountain	675	-5.2%
Pacific	1,400	3.8%
Other	41	11.0%
Facility Size (Number of 1st Episodes)		
< 100 episodes	2,841	1.9%
100 to 249	2,301	1.1%
250 to 499	2,218	0.6%
500 to 999	1,636	-0.3%
1,000 or More	1,484	-0.2%
Nursing/Therapy Visits Ratio		
1st Quartile (Lowest 25% Nursing)	2,620	-9.9%
2nd Quartile	2,620	-0.8%
3rd Quartile	2,620	6.5%
4th Quartile (Top 25% Nursing)	2,620	17.0%

Source: CY 2017 Medicare claims data (as of March 2, 2018) for episodes ending on or before December 31, 2017 for which we had a linked OASIS assessment.

Note(s): The "PDGM" is the 30-day version of the model with no behavioral assumptions applied. From the impact file, this analysis omits 354,099 60-day episodes not grouped under the PDGM (either due to a missing SOC OASIS, because they could be assigned to a clinical grouping, or had missing therapy/nursing visits). After converting 60-day episodes to 30-day periods for the PDGM, a further 26 periods were excluded with missing NRS weights, and 2,386 periods with a missing urban/rural indicator. These excluded episodes results overall in 67 fewer HHAs being represented than in the standard impact tables.

REGION KEY:
New England=Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Middle Atlantic=Pennsylvania, New Jersey, New York
South Atlantic=Delaware, District of Columbia, Florida, Georgia, Maryland, North Carolina, South Carolina, Virginia, West Virginia
East North Central=Illinois, Indiana, Michigan, Ohio, Wisconsin
East South Central=Alabama, Kentucky, Mississippi, Tennessee
West North Central=Iowa, Kansas, Minnesota, Missouri, Nebraska, North Dakota, South Dakota
West South Central=Arkansas, Louisiana, Oklahoma, Texas
Mountain=Arizona, Colorado, Idaho, Montana, Nevada, New Mexico, Utah, Wyoming
P**acific**=Alaska, California, Hawaii, Oregon, Washington
Other=Guam, Puerto Rico, Virgin Islands

In response to the CY 2019 case-mix adjustment methodology refinements proposed in the CY 2018 HH PPS proposed rule (82 FR 35270), a few commenters requested that CMS include more information in the impact table for the proposed PDGM, specifically how payments are impacted for patients with selected clinical conditions as was included in the Technical Report which is available at: https://downloads.cms.gov/files/hhgm%20technical%20report%20120516%20sxf.pdf. Therefore, we are including Table 61 which provides more information on the impact of the PDGM case-mix adjustment methodology for patients with selected clinical conditions.

TABLE 61: IMPACT OF THE PDGM FOR SELECTED PATIENT CHARACTERISTICS

	Ratio of Average PDGM Payment to Average Current (30-Day Equivalent) Payment
All Episodes (60-Day Count)	**1.00**
Clinical Group	
Behavioral Health	0.85
Complex	1.13
MMTA	1.00
MS Rehab	0.96
Neuro Rehab	0.93
Wound	1.27
Functional Level	

	Ratio of Average PDGM Payment to Average Current (30-Day Equivalent) Payment
Low	0.95
Medium	1.00
High	1.05
Admission Source	
Community	0.89
Institutional	1.30
Timing	
Early	1.25
Late	0.87
Comorbidity Group	
No adjustment	0.97
Single Comorbidity	1.02
Comorbidity Interaction	1.22
Dual Status	
Not (Full) Dual Eligible	0.99
Yes (Full) Dual Eligible	1.03
Parenteral Nutrition	
No Parenteral Nutrition	1.00
Yes Parenteral Nutrition	1.18
Surgical Wounds	
No Known Surgical Wound	0.98
Yes Known Surgical Wound	1.11
Ulcers	
No Ulcers Recorded	0.99
Positive Number of Ulcers Recorded	1.16
Bathing	
Able to Bathe with some independence	0.97
Cannot bathe independently	1.08
Poorly-Controlled Cardiac Dysrhythmia	
No Poorly-Controlled Cardiac Dysrhythmia	1.00
Yes Poorly-Controlled Cardiac Dysrhythmia	1.04
Poorly-Controlled Diabetes	
No Poorly-Controlled Diabetes	0.99
Yes Poorly-Controlled Diabetes	1.06
Poorly-Controlled Peripheral Vascular Disease	
No Poorly-Controlled Peripheral Vascular Disease	1.00
Yes Poorly-Controlled Peripheral Vascular Disease	1.07
Poorly-Controlled Pulmonary Disorder	
No Poorly-Controlled Pulmonary Disorder	1.00
Yes Poorly-Controlled Pulmonary Disorder	1.03
Open Wound/Lesion	
No Open Wound/Lesion	0.98
Yes Open Wound/Lesion	1.10
Temporary Health Risk	
No Temporary Health Risk	0.99
Yes Temporary Health Risk	1.02
Fragile/Serious Health Risk	
Yes Fragile/Serious Health Risk	0.98
No Fragile/Serious Health Risk	1.04

Note(s): **For this table only**, payments are for normal episodes and do not include outlier payments. For comparability with the 30-day PDGM, current payments have been halved from 60-day amounts to simulate 30-day payments. PDGM payments have been normalized so that national average 30-day payments equaled the 30-day current system equivalent payment to facilitate an understanding of reallocation of payments from the current system. For the ratio of PDGM to current payments in the right-hand column, a value greater than one signifies that characteristic would receive increased payment and a value less than one would signify that characteristic would receive lesser payment, all else equal, in the PDGM. To be classified as Poorly Controlled Cardiac Dysrhythmia, Diabetes, Peripheral Vascular Disease, or Pulmonary Disorder required one of the following respective primary or secondary diagnosis codes with an accompanying recorded "poorly-controlled" degree of symptom control: Cardiac Dysthymia: ICD-10 I-21-I22.9 & I47-I49; Diabetes: E08.0-E08.8, E09.0-E09.8, & E10-E14; Peripheral Vascular Disease: ICD-10 I73; and Pulmonary Disorder: (I40-47, J84.01, J84.02, J84.03, J84.10, J96.0-J96.92, & J98.01-J98.3).

2. HHVBP Model

Table 62 displays our analysis of the distribution for possible payment adjustments at the maximum 7-percent, and 8-percent rates that will be used in Years 4 and 5 of the Model. These analyses use performance year data from 2016, the first year of HHVBP, the most recent year for which complete performance year data are available. The estimated impacts are for the following proposed changes, each of which would take effect beginning with PY4 (2019):

- Remove two OASIS-based measures (Influenza Immunization Received for Current Flu Season and Pneumococcal Polysaccharide Vaccine Ever Received);
- Replace three OASIS-based measures (Improvement in Bathing, Improvement in Bed Transferring, and Improvement in Ambulation-Locomotion) with two composite measures (Total Change in Self Care, Total Change in Mobility). The two composite measures would have a maximum score of 15 points;
- Reduce the maximum possible improvement points from 10 to 9 (13.5 for the two composite measures); and,
- Change the weights given to the performance measures used in the Model so that the OASIS and claims-based measures each count for 35 percent and the HHCAHPS measures count for 30 percent of the 90 percent of the Total Performance Score (TPS) that is based on performance on the Clinical Quality of Care, Care Coordination and Efficiency, and Person and

Caregiver-Centered Experience measures. Data reporting for each New Measure would continue to have equal weight and account for the 10 percent of the TPS that is based on the New Measures collected as part of the Model. The weight of the unplanned hospitalization measure would also be increased so that it has three times the weight of the ED use without hospitalization measure.

We analyzed the payment adjustment percentage and the number of eligible HHAs under current policy to determine the impacts if the proposed changes in this rule were finalized. We used PY1 (CY2016) data to measure the impacts. The data sources for these analyses are data from the QIES system for the existing OASIS and claims-based measures, OASIS assessments for the two composite measures, HHCAHPS data received from the HHCAHPS contractor, and New Measure data submitted by Model participants. HHAs are classified as being in the smaller or larger volume cohort using the 2016 Quality Episode File, which is created using OASIS assessments. We note that this impact analysis is based on the aggregate value across all nine Model states.

Table 63 displays our analysis of the estimated impact of the proposals in this rule on the number of eligible HHAs and the distribution of percentage change in payment adjustment percentage based on the same PY1 (CY2016) data used to calculate Table 62. We note that this impact analysis is based on the aggregate value across all nine Model states. Note that all Medicare-certified HHAs that provide services in Massachusetts, Maryland, North Carolina, Florida, Washington, Arizona, Iowa, Nebraska, and Tennessee are required to compete in this Model. The analysis is calculated at the state and size cohort level. It is expected that a certain number of HHAs would not have a payment adjustment because they may be servicing too small of a population to report an adequate number of measures to calculate a TPS. Table 63

shows that there would be a reduction in the number of HHAs that would have a sufficient number of measures to receive a payment adjustment for performance year 4 of 31 HHAs (Change column), a decrease from 1,610 HHAs (Current column) to 1,579 HHAs (Simulated column) across the nine selected states.

This analysis reflects only HHAs that would have data for at least five measures that meet the requirements of §484.305 and would be included in the LEF and would have a payment adjustment calculated. Value-based incentive payment adjustments for the estimated eligible 1,579 HHAs in the selected states that would compete in the HHVBP Model are stratified by size as described in section IV.B. of the CY 2017 HH PPS final rule. As finalized in section IV.B. of the CY 2017 final rule, there must be a minimum of eight HHAs in any cohort.

Those HHAs that are in states that do not have at least eight smaller-volume HHAs will not have a separate smaller-volume cohort and thus there will only be one cohort that will include all the HHAs in that state. As indicated in Table 63, Maryland, North Carolina, Tennessee, Washington, and Arizona would have only one cohort while Florida, Iowa, Massachusetts, and Nebraska would have both a smaller-volume cohort and a larger-volume cohort. For example, Iowa would have 17 HHAs eligible to be exempt from being required to have their beneficiaries' complete HHCAHPS surveys because they provide HHA services to less than 60 beneficiaries. Therefore, those 17 HHAs would be competing in Iowa's smaller-volume cohort for CY 2019 (PY4) under the Model.

Table 63 shows the distribution of percentage change in payment adjustment percentage resulting from the proposals in this rule. Using 2016 data and the maximum payment adjustment for performance year 4 of 7 percent (as applied in CY 2021), based on the six

proposed OASIS quality measures and two claims-based measures in QIES, the five HHCAHPS measures, and the three New Measures, we see that, across all nine states, 31 HHAs would no longer be eligible for a payment adjustment for PY4 because they would not have data on at least five measures that meet the requirements of §484.305. The distribution of scores by percentile shows the distribution of the change in percent payment adjustment. For example, the distribution for HHAs in Florida in the smaller-volume cohort ranges from -2.5 percent at the 10th percentile to +2.9 percent at the 90th percentile. This means that, for 7 of the 77 HHAs in the smaller-volume cohort in Florida, the proposed changes would decrease their payment adjustment percentage by -2.5 percent or more while, for another 7 HHAs these proposed changes would increase their payment adjustment percentage by 2.9 percent or more. For half of the HHAs in Florida's smaller volume cohort, the impact of these proposed changes on their payment adjustment percentage would be between -1.1 percent and +1.3 percent. These impact analyses suggest that, for most participating HHAs, the impacts of the proposed changes would be modest.

Table 64 provides the payment adjustment distribution based on agency size, proportion of dually-eligible beneficiaries, average case mix (using the average case-mix for non-LUPA episodes), the proportion of the HHA's beneficiaries that reside in rural areas and HHA organizational status. HHAs with a higher proportion of dually-eligible beneficiaries and HHAs whose beneficiaries have higher acuity tend to have a more negative impact associated with the proposals in this rule based on the 50th percentile of the impact of the changes on payment adjustment percentage.

Table 65 shows the current and proposed weights for individual performance measures by measure category and possible applicable measure category scenarios to demonstrate the

weight of the individual measures when an HHA has scores on All Measures or if an HHA is missing all measures in a measure category. For example, for an HHA that has quality measure scores on All Measures in all the measure categories (OASIS-based, claims-based and HHCAHPS) under the current weighting method, the individual measures are weighted equally. The Proposed Weights columns show the proposed weights for the individual performance measures based on the changes to the weighting methodology proposed in this rule. For example, for HHAs with scores on All Measures, the OASIS-based measures account for 35 percent of the TPS, with equal weighting given to the Improvement in Oral Medications, Improvement in Dyspnea, Improvement in Pain, and Discharge to Community measures. The proposed Composite Self-Care and Composite Mobility measures would be weighted 1.5 times more than the other OASIS-based measures so that the maximum score for the two composite measures is the same as for the three functional OASIS-based measures that they would replace (Improvement in Ambulation, Bathing and Bed Transferring). Under the proposed weights, the two claims-based measures, which would collectively account for 35 percent of an HHA's TPS, would not be weighted equally. We are proposing that the weight of the acute care hospitalization measure would be three times higher than that of the ED Use measure. Thus, its weight would be 26.25 percent while the weight of the ED Use measure would be 8.75 percent for an HHA that reported on all measures. The HHCAHPS measures would account for 30 percent of an HHA's TPS and each measure would be weighted equally.

Table 65 also shows the number of HHAs that would have enough measures to receive a payment adjustment under each possible scoring scenario under both the current and proposed weighting methodologies. Most of the HHAs that would no longer receive a payment adjustment with the proposed changes in this rule are those with no claims or HHCAHPS

measures. With only OASIS measures, these HHAs are more impacted by the proposal to remove the two immunization measures and the proposal to replace three OASIS functional measures with the two composite measures. The number of HHAs without claims or HHCAHPS measures that do not have enough measures to receive a payment adjustment would drop from 99 to 73 (a decrease of 26 HHAs), and the majority of the HHAs that would no longer have a payment adjustment would be smaller HHAs (16 of the 26 HHAs).

TABLE 62: ADJUSTMENT DISTRIBUTION BY PERCENTILE LEVEL OF QUALITY TOTAL PERFORMANCE SCORE AT DIFFERENT MODEL PAYMENT ADJUSTMENT RATES (PERCENTAGE)

		Percentile								
Payment Adj. Distribution	**Maximum Payment Adjustment Percentage**	**10%**	**20%**	**30%**	**40%**	**Median**	**60%**	**70%**	**80%**	**90%**
7% Payment Adj. For PY4 of the Model	7%	-3.3%	-2.4%	-1.7%	-0.9%	-0.2%	0.5%	1.2%	2.2%	3.7%
8% Payment Adj. For PY5 of the Model	8%	-3.8%	-2.8%	-1.9%	-1.0%	-0.3%	0.5%	1.4%	2.5%	4.2%

TABLE 63: HHA COHORT PAYMENT ADJUSTMENT DISTRIBUTIONS BY STATE/COHORT
[Based on a 7-percent payment adjustment]

		Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Proposed Changes				
State	**Cohort**	**Current**	**Simulated**	**Change**	**10th Percentile**	**25th Percentile**	**50th Percentile**	**75th Percentile**	**90th Percentile**
	All	1610	1579	31	-2.1%	-1.0%	-0.1%	0.9%	1.9%
HHAs with no separate small HHA cohort									
AZ	All	113	112	1	-2.7%	-1.4%	-0.1%	0.7%	1.8%
MD	All	51	50	1	-1.7%	-0.6%	-0.3%	0.9%	1.6%
NC	All	163	163	0	-1.6%	-0.8%	0.0%	0.7%	1.9%
TN	All	122	122	0	-1.2%	-0.7%	0.2%	0.8%	1.7%
WA	All	57	57	0	-1.3%	-0.8%	0.0%	0.8%	2.0%
Large-volume HHA Cohort in states with small cohort									
FL	Large	706	703	3	-2.3%	-1.2%	-0.2%	1.0%	2.0%
IA	Large	99	97	2	-1.9%	-1.2%	-0.2%	0.8%	1.5%
MA	Large	123	119	4	-2.0%	-1.1%	-0.4%	0.5%	1.4%
NE	Large	45	45	0	-2.8%	-0.9%	-0.3%	0.6%	1.8%
Small-volume HHA Cohort in states with small cohort									
FL	Small	77	68	9	-2.5%	-1.1%	0.1%	1.3%	2.9%
IA	Small	25	17	8	0.1%	1.3%	2.9%	4.4%	6.4%
MA	Small	15	12	3	-1.4%	-0.5%	0.3%	1.5%	2.2%
NE	Small	14	14	0	-3.0%	-1.0%	0.0%	1.2%	2.2%

TABLE 64: PAYMENT ADJUSTMENT DISTRIBUTIONS BY CHARACTERISTICS FOR THE HHVBP MODEL
[Based on a 7-percent payment adjustment [1, 2]]

	Number of Eligible HHAs			Distribution of Percentage Change in Payment Adjustment Percentage Resulting From Proposed Changes				
Cohort	**Current**	**Simulated**	**Change**	**10th Percentile**	**25th Percentile**	**50th Percentile**	**75th Percentile**	**90th Percentile**
Facility size (# of patients)								
Small HHA	136	117	19	-3.2%	-1.6%	-0.2%	1.1%	3.1%
Large HHA	1474	1462	12	-2.0%	-1.0%	-0.1%	0.9%	1.9%
Percentage of Medicaid patients								
No Medicaid	749	743	6	-2.2%	-1.1%	-0.1%	0.9%	2.0%
>0 and < 30% Medicaid	661	653	8	-1.7%	-0.9%	0.0%	0.9%	1.9%
30%+ Medicaid	200	183	17	-2.6%	-1.4%	-0.4%	0.6%	1.8%
Patient acuity								
Low Acuity	403	384	19	-2.2%	-1.0%	-0.1%	1.0%	2.0%
Medium Acuity	805	798	7	-1.8%	-0.9%	0.0%	0.9%	1.9%
High Acuity	402	397	5	-2.3%	-1.3%	-0.3%	0.9%	2.0%
Percentage of rural beneficiaries								
None	1482	1458	24	-2.1%	-1.1%	-0.1%	0.9%	1.9%
> 0 and < 90%	11	10	1	-4.1%	-1.1%	-0.4%	0.3%	1.7%
>=90%	117	111	6	-1.7%	-0.9%	0.2%	1.5%	2.7%
Facility type and control								
Non-profit	310	308	2	-1.4%	-0.8%	0.2%	1.0%	1.9%
For profit	1191	1169	22	-2.2%	-1.1%	-0.2%	0.8%	1.9%
Government	109	102	7	-1.9%	-0.9%	0.0%	1.2%	2.7%
Freestanding	1448	1419	29	-2.1%	-1.1%	-0.2%	0.9%	1.9%
Facility-based	162	160	2	-1.2%	-0.5%	0.2%	1.1%	2.0%

[1] Rural beneficiaries identified based on the CBSA code reported on the claim.

[2] Acuity is based on the average case-mx weight for non-LUPA episodes. Low acuity is defined as the bottom 25% (among HHVBP model participants); mid-acuity is the middle 50% and high acuity is the highest 25%.

TABLE 65: CURRENT AND PROPOSED WEIGHTS FOR INDIVIDUAL PERFORMANCE MEASURES FOR THE HHVBP MODEL [1234]

	Current Weights				Proposed Weights: All Changes				Proposed Weights: Reweighting Changes Only			
	All Measures (n=1,026)	**No HHCAHPS (n=465)**	**No claims (n=20)**	**No claims or HHCAHPS (n=99)**	**All Measures (n=1,026)**	**No HHCAHPS (n=460)**	**No claims (n=20)**	**No claims or HHCAHPS (n=73)**	**All Measures (n=1,026)**	**No HHCAHPS (n=460)**	**No claims (n=20)**	**No claims or HHCAHPS (n=73)**
Large HHAs	*1023*	*382*	*20*	*49*	*1023*	*380*	*20*	*39*				
Small HHAs	*3*	*83*	*0*	*50*	*3*	*80*	*0*	*34*				
OASIS (35% weight)*												
Flu vaccine ever received**	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Pneumococcal vaccine**	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Bathing***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Bed Transfer***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Ambulation***	6.25%	9.09%	7.14%	11.11%	0.00%	0.00%	0.00%	0.00%	3.89%	5.56%	5.98%	11.11%
Improve Oral Meds	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Improve Dyspnea	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Improve Pain	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Discharge to Community	6.25%	9.09%	7.14%	11.11%	5.00%	7.14%	7.69%	14.28%	3.89%	5.56%	5.98%	11.11%
Composite self-care	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%	0.00%	0.00%	0.00%	0.00%
Composite mobility	0.00%	0.00%	0.00%	0.00%	7.50%	10.71%	11.53%	21.42%	0.00%	0.00%	0.00%	0.00%
Total weight for OASIS measures	*56.25%*	*81.82%*	*64.26%*	*100.00%*	*35.00%*	*49.98%*	*53.82%*	*99.96%*	*35.00%*	*50.00%*	*53.85%*	*100.00%*
Claims (35% weight)												
Hospitalizations	6.25%	9.09%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%	26.25%	37.50%	0.00%	0.00%
Outpatient ED	6.25%	9.09%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%	8.75%	12.50%	0.00%	0.00%
Total weight for claims measures	*12.50%*	*18.18%*	*0.00%*	*0.00%*	*35.00%*	*50.00%*	*0.00%*	*0.00%*	*35.00%*	*50.00%*	*0.00%*	*0.00%*
HHCAHPS (30% weight)												
Care of patients	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Communication between provider and patient	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Discussion of specific care Issues	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Overall rating of care	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Willingness to recommend HHA to family or friends	6.25%	0.00%	7.14%	0.00%	6.00%	0.00%	9.23%	0.00%	6.00%	0.00%	9.23%	0.00%
Total weight for HHCAHPS measures	*31.25%*	*0.00%*	*35.70%*	*0.00%*	*30.00%*	*0.00%*	*46.15%*	*0.00%*	*30.00%*	*0.00%*	*46.15%*	*0.00%*

[1] Under the proposal if individual OASIS items are missing, the weight of the non-missing OASIS items would be increased.

[2] Flu vaccine ever received and the pneumococcal polysaccharide vaccine measures are proposed to be removed from the applicable measure set beginning in CY 2019/PY4.

[3] Improvement in Bathing, Bed Transfer and Ambulation measures are proposed to be removed if proposed composite measures are added to the applicable measure set beginning in CY 2019/PY4.

[4] The proposed composite measures (Composite Self-Care and Composite Mobility) would replace three functional OASIS-based measures (Improvement in Bathing, Improvement in Bed Transfer, Improvement in Ambulation), thus they would be weighted 1.5 times more than the other OASIS-based measures so that the total weight for the functional-based OASIS measures is unchanged.

3. HH QRP

Failure to submit data required under section 1895(b)(3)(B)(v) of the Act with respect to a calendar year will result in the reduction of the annual home health market basket percentage increase otherwise applicable to a HHA for that calendar year by 2 percentage points. For the CY 2018 annual payment update determination, 1,311 of the 11,776 active Medicare-certified HHAs, or approximately 11.1 percent, did not receive the full annual percentage increase. Information is not available to determine the precise number of HHAs that would not meet the requirements to receive the full annual percentage increase for the CY 2019 payment determination.

As discussed in section V.E. of this proposed rule, we are proposing to remove seven measures from the HH QRP: Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in the Status of Surgical Wounds, Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505), Rehospitalization during the First 30 Days of HH (NQF #2380). All seven of these measures are proposed for removal starting with the CY 2021 HH QRP. As noted previously, section VII. of this proposed rule provides a detailed description of the net decrease in burden associated with these proposed changes in conjunction with the changes in burden that result from the proposed implementation of the PDGM for CY 2020. We estimate that the burden associated with OASIS item collection as a result of this proposed rule results in a net $60 million in annualized cost savings to HHAs, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

4. Home Infusion Therapy Payment

The following analysis applies to the Temporary Transitional Payment for Home Infusion Therapy as set forth in section 1834(u)(7) of the Act, as added by section 50401 of the BBA of 2018 (Pub. L 115-123), and accordingly, describes the impact for CY 2019 only. Table 66 represents the estimated increased costs of existing DME users currently using home infusion therapy services. We used CY 2017 data to identify beneficiaries with DME claims containing 1 of the 37 HCPCS codes identified in section 1834(u)(7)(C) of the Act, which are shown in column 2. In column 3, 2017 claims were again used to determine the total weeks of care, which is the sum of weeks of care across all beneficiaries found in each category. Weeks of care for payment categories 1 and 3 are defined as the week of the last infusion drug or pump claim minus the week of the first infusion drug or pump claim plus one. For Category 2, we used the median number of weeks of care, 47, as many patients use immune globulin for the whole year. Column four assumes the initial week of care requires two nurse visits, and all subsequent weeks only require one visit, in order to estimate the total visits of care per category. In general, nursing visits for payment category 2, subcutaneous immune globulin (SCIG) administration, occur once per month; therefore, we assume the estimated number of visits for these patients is 12. The fifth column multiplies the volume of nurse visits across beneficiaries by the payment rate (using the 2018 Physician Fee Schedule amounts) in order to estimate the increased cost per each of the three infusion drug categories. [112] In the CY 2019 HH PPS final rule, we will update this impact analysis using more complete 2017 claims data (as of June 30, 2018 or later) and the CY 2019 Physician Fee Schedule amounts.

[112] Based on the 2018 Medicare PFS these rates are $141.12 ($74.16+3*$22.32) for Category 1, $224.28 ($176.76+3*$15.84) for Category 2, and $239.76 ($144.72+3*$31.68) for Category 3.

TABLE 66: ESTIMATED INCREASED COSTS OF EXISTING DME HOME INFUSION PATIENTS NOW RECEIVING COVERED HOME INFUSION THERAPY SERVICES, CY 2019

Payment Category	Number of Beneficiaries	Total Weeks of Care	Estimated Total Visits of Care	2018 Payment Rate	Estimated Cost
1	5,885	130,896	136,781	$141.12	$19,302,535
2	6,315	236,470	75,780	$224.28	$16,995,938
3	5,774	87,260	93,034	$239.76	$22,305,832
Total	17,974				$58,604,305

Table 67 displays the estimated regional impacts using the beneficiary enrollment address reported in the Medicare Master Beneficiary Summary File. Table 68 displays impacts based on rural or urban designations. All beneficiaries identified had at least one applicable home infusion claim (claims with 1 of the 37 drug codes listed in section 1834(u)(7)(C) of the Act) in CY 2017. Unknown beneficiaries were those without valid state and county information in the Master Beneficiary Summary File. Additionally, the tables provide the estimated impacts by drug category.

TABLE 67: ESTIMATED IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES BY REGION, CY 2019

Census Region	Number of Home Infusion Patients	Category 1	Category 2	Category 3	Total
New England	719	$1,030,740.48	$866,617.92	$$263,496.24	$2,160,854.64
Mid Atlantic	3,503	$2,699,343.36	$1,582,519.68	$8,670,920.40	$12,952,783.44
East North Central	2,493	$3,204,976.32	$1,733,235.84	$3,346,330.32	$8,284,542.48
West North Central	1,296	$1,192,605.12	$1,351,062.72	$1,644,034.32	$4,187,702.16
South Atlantic	4,396	$4,367,805.12	$4,849,830.72	$4,516,359.12	$13,733,994.96
East South Central	1,201	$1,330,761.60	$1,544,840.64	$668,690.64	$3,544,292.88
West South Central	1,729	$2,546,228.16	$1,824,742.08	$942,256.80	$5,313,227.04
Mountain	847	$978,949.44	$1,404,889.92	$281,957.76	$2,665,797.12
Pacific	1,727	$1,928,969.28	$1,800,519.84	$1,882,595.52	$5,612,084.64
Other	63	$22,155.84	$37,679.04	$89,190.72	$149,025.60
Total	17,974	$19,302,534.72	$16,995,938.40	$22,305,831.84	$58,604,304.96

TABLE 68: ESTIMATED URBAN/RURAL IMPACTS OF THE TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSION THERAPY SERVICES, CY 2019

CBSA Urban/Rural	Number of Home Infusion Patients	Category 1	Category 2	Category 3	Total
Urban	14,692	$15,906,058.56	$14,495,664.96	$17,419,762.80	$47,821,486.32
Rural	3,239	$3,384,057.60	$2,462,594.40	$4,863,052.08	$10,709,704.08

Unknown	43	$12,418.56	$37,679.04	$23,016.96	$73,114.56
Total	17,974	$19,302,534.72	$16,995,938.40	$22,305,831.84	$58,604,304.96

E. Alternatives Considered

1. HH PPS

a. HH PPS for CY 2019

Section 1895(b)(3)(B) of the Act requires that the standard prospective payment amounts for CY 2019 be increased by a factor equal to the applicable HH market basket update for those HHAs that submit quality data as required by the Secretary. For CY 2019, Section 1895(b)(3)(B)(vi) of the Act requires that the market basket update under the HHA prospective payment system be annually adjusted by changes in economy-wide productivity. The proposed 0.7 percentage point multifactor productivity adjustment to the proposed CY 2019 home health market basket update of 2.8 percent, is discussed in the preamble of this rule and is not discretionary as it is a requirement in section 1895(b)(3)(B)(vi)(I) of the Act.

We considered not rebasing the home health market basket. However, we believe that it is desirable to rebase the home health market basket periodically so that the cost category weights reflect changes in the mix of goods and services that HHAs purchase in furnishing home health care. In addition, we considered not implementing the proposed revision to the labor-related share of 76.1 percent in a budget neutral manner. However, we believe it is more prudent to implement the revision to the labor-related share in a manner that does not increase or decrease budgetary expenditures.

With regards to payments made under the HH PPS for high-cost outlier episodes of care (that is, episodes of care with unusual variations in the type or amount of medically necessary care), we did not consider maintaining the current FDL ratio of 0.55. As discussed in section III.E.3. of this proposed rule, we propose to revise the FDL ratio to 0.51. Simulations using CY

2017 claims data and the proposed CY 2019 HH PPS payment rates resulted in an estimated 2.32 percent of total HH PPS payments being paid as outlier payments using the existing methodology for calculating the cost of an episode of care. The FDL ratio and the loss-sharing ratio must be selected so that the estimated outlier payments do not exceed the 2.5 percent of total HH PPS payments (as required by section 1895(b)(5)(A) of the Act). We did not consider proposing a change to the loss sharing ratio (0.80) in order for the HH PPS to remain consistent with payment for high-cost outliers in other Medicare payment systems (for example, IRF PPS, IPPS, etc.)

b. HH PPS for CY 2020 (PDGM)

For CY 2020, we did not consider alternatives to changing the unit of payment from 60 days to 30 days, eliminating the use of therapy thresholds for the case-mix adjustment, and requiring the revised payments to be budget neutral. Section 51001 of the BBA of 2018 requires the change in the unit of payment from 60 days to 30 days to be made in a budget neutral manner and mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes. The BBA of 2018 also requires these measures to be implemented on January 1, 2020 and that we make assumptions about behavior changes that could occur as a result of the implementation of the 30-day unit of payment and as a result of the case-mix adjustment factors that are implemented in CY 2020 in calculating a 30-day payment amount for CY 2020 in a budget neutral manner.

Alternatives to making 19 current OASIS items (48 data elements) optional at the FU time point as outlined in section VII. of this proposed rule, would be to either not implement the case-mix adjustment methodology changes proposed under the PDGM or to continue collecting the 19 current OASIS items at the FU time point, even though they would not be used to case-

mix adjust payments under the PDGM. Similarly, an alternative to adding collection of two current OASIS items (10 data elements) at the FU time point as discussed in section VII. of this proposed rule would be to either not adopt the PDGM or not to include the two current OASIS items (M1800 and M1033) as part of the case-mix adjustment methodology under the proposed PDGM. As noted previously, we did not consider not implementing the case-mix methodology changes under the proposed PDGM as a new case-mix adjustment methodology is required to be implemented in accordance with section 51001 of the BBA of 2018, which mandates the elimination of the use of therapy thresholds for case-mix adjustment purposes by January 1, 2020. We believe that continuing to require HHAs to report responses for the 19 current OASIS items at the FU time point that are no longer needed for case-mix adjustment purposes under the PDGM results in unnecessary burden for HHAs. While requiring HHAs to report responses for two current OASIS items at the FU time point results in a small increase in burden if CMS were to not make 19 current OASIS items optional at the FU time point, those two OASIS items (M1800 and M1033) are correlated with increases in resource use and are used to determine the patient's functional impairment level under the HHGM, thus they are important for case-mix adjustment purposes in order to ensure accurate payments to HHAs under the proposed PDGM.

We considered whether to continue using the wage-weighted minutes of care (WWMC) approach to estimate resource use under the PDGM, as described in section III.F.2. of this proposed rule. Although the relationship in relative costs between the WWMC approach and the proposed cost-per-minute plus non-routine supplies (CPM+NRS) approach is very similar (correlation coefficient equal to 0.8512), the WWMC approach does not as evenly weight skilled nursing costs relative to therapy costs as evidenced in the cost report data and would

require us to maintain a separate case-mix adjustment mechanism for NRS. If we were to maintain the current WWMC approach, skilled nursing and therapy costs would not be as evenly weighted and a certain level of complexity in calculating payments under the HH PPS would persist as we would need to continue with the current method of case-mix adjusting NRS payments separate from service costs (that is, skilled nursing, physical therapy, occupational therapy, speech-language pathology, home health aide, and medical social services) under the HH PPS.

In this proposed rule and to begin in CY 2020, we considered proposing a phase-out of the split percentage payment approach by reducing the percentage of the upfront payment over a period of time and requiring a notice of admission (NOA) to be submitted upon full elimination of the split-percentage payment. However, we wanted to take the opportunity in this year's rule to more clearly signal our intent to potentially eliminate the split percentage payment approach over time as a reduced timeframe for the unit of payment (30 days rather than 60 days) is now required in statute. Given that existing HHAs (certified with effective dates prior to January 1, 2019) would need to adapt to changes in cash flow with the elimination of the split percentage payment approach, we hope to receive additional feedback on the timeframes for a phase-out of the split percentage payment approach and whether there is a need for an NOA upon completion of a phase-out of the split percentage payment approach that we can take into consideration for potential future rulemaking.

2. HHVBP Model

An alternative to our proposal to remove the two vaccination measures beginning with PY 4 would be to continue to include them in the applicable measure set.

An alternative to our proposal to replace three OASIS-based measures with two

proposed composite measures would be to make no changes to the OASIS-based measures category.

Another alternative to this proposal would be to finalize one but not both composite measures. All three of the ADL measures that would be replaced (Improvement in Bathing, Improvement in Bed Transferring, Improvement in Ambulation-Locomotion) relate to the normalized change in self-care measure, so, if only the self-care measure were adopted it would replace the three individual ADL items and count for 30 points. If only the mobility composite measure were adopted, however, it would count for 15 points and the three individual measures (which would not be dropped) would count for 5 points each. That would keep the relative points for the ADL measures at 30 no matter which option were adopted.

An alternative to rescoring the maximum improvement points from 10 points to 9 points would be to keep the current scoring methodology.

An alternative to reweighting the OASIS-based, claims-based and HHCAHPS measure categories would be to keep the current equally weighted methodology.

3. HH QRP

An alternative to removing seven measures from the HH QRP (Depression Assessment Conducted, Diabetic Foot Care and Patient/Caregiver Education Implemented during All Episodes of Care, Multifactor Fall Risk Assessment Conducted For All Patients Who Can Ambulate (NQF #0537), Pneumococcal Polysaccharide Vaccine Ever Received, Improvement in the Status of Surgical Wounds, Emergency Department Use without Hospital Readmission during the First 30 Days of HH (NQF #2505), Rehospitalization during the First 30 Days of HH (NQF #2380)), as discussed in section V.E. of this proposed rule would be to retain these measures in the HH QRP.

4. Home Infusion Therapy

a. Health and Safety Standards

We considered establishing additional requirements related to patient assessment, infection control and quality improvement. However, according to the home infusion therapy supplier industry, and our research, we believe there are already AO standards that include requirements related to patient assessment, quality improvement, and infection control. While the exact content of the AO standards vary, we believe that the standards are adequate to ensure basic patient health and safety.

b. Payment

We did not consider alternatives to implementing the home infusion therapy benefit for CY 2019 and 2020 because section 1834(u)(7) of the Act requires the Secretary to provide a temporary transitional payment to eligible home infusion therapy suppliers for items and services associated with the furnishing of transitional home infusion drugs.

c. Accreditation of Qualified Home Infusion Therapy Suppliers

AOs that accredit home infusion therapy suppliers must become accredited by an AO designated by the Secretary. In these options, we have attempted to minimize the burden of accreditation on home infusion therapy suppliers, which include approving home infusion therapy AOs that consider the unique needs of small home infusion therapy suppliers. Also, it is likely that the surveys of home infusion therapy suppliers would be performed as a desk review instead of an onsite survey. Doing a desk audit survey would prevent the travel time and cost that is required when the AO has to send a survey team to the home infusion therapy supplier's location to perform an onsite survey.

F. Accounting Statement and Tables

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), in Table 69, we have prepared an accounting statement showing the classification of the transfers and costs associated with the CY 2019 HH PPS provisions of this rule. For CY 2020, due to the section 51001(a) of the BBA of 2018 requirement that the transition to the 30-day unit of payment be budget neutral, Table 70 displays a transfer of zero. Table 71 provides our best estimates of the changes to OASIS item collection as a result of the proposed implementation of the PDGM and proposed changes to the HH QRP. Table 72 provides our best estimate of the increase in Medicare payments to home infusion therapy suppliers related to the temporary transitional payment for home infusion therapy in CY 2019. Table 73 provides our best estimate of cost of AO compliance with our proposed home infusion the Infusion Therapy requirements.

TABLE 69: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers	$400 million
From Whom to Whom?	Federal Government to HHAs

TABLE 70: ACCOUNTING STATEMENT: HH PPS CLASSIFICATION OF ESTIMATED TRANSFERS DUE TO THE PDGM PROPOSALS, FROM CY 2019 TO 2020 PDGM

Category	Transfers
Annualized Monetized Transfers	$0 million
From Whom to Whom?	HHAs to Federal Government

TABLE 71: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS OF OASIS ITEM COLLECTION, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden for HHAs' Submission of the OASIS	-$60 million

TABLE 72: ACCOUNTING STATEMENT: TEMPORARY TRANSITIONAL PAYMENT FOR HOME INFUSTION THERAPY CLASSIFICATION OF ESTIMATED TRANSFERS, FROM CY 2018 TO 2019

Category	Transfers
Annualized Monetized Transfers	$60 million
From Whom to Whom?	Federal Government to Home Infusion Therapy Suppliers

TABLE 73: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS FOR HOME INFUSION THERAPY ACCREDITATION ORGANIZATIONS, FROM CY 2019 TO CY 2020

Category	Costs
Annualized Monetized Net Burden to Each Home Infusion Therapy AO for Compliance with the Proposed Regulations at §§488.1010 through 488.1050	$23,258

G. Regulatory Reform Analysis under EO 13771

Executive Order 13771, entitled "Reducing Regulation and Controlling Regulatory Costs," was issued on January 30, 2017 and requires that the costs associated with significant new regulations "shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least two prior regulations." Details on the estimated costs of this proposed rule, including limitations on the ability thus far to quantify some categories of impacts, can be found in the rule's economic analysis. The determination of this proposed rule's status as a regulatory or deregulatory action for the purposes of Executive Order 13771 will be informed by comments received in response to this proposed rulemaking.

H. Conclusion

1. HH PPS

a. HH PPS for CY 2019

In conclusion, we estimate that the net impact of the HH PPS policies in this rule is an

increase of 2.1 percent, or $400 million, in Medicare payments to HHAs for CY 2019. The $400 million increase reflects the effects of the CY 2019 home health payment update of 2.1 percent ($400 million increase), a 0.1 percent increase in payments due to decreasing the FDL ratio in order to target to pay no more than 2.5 percent of total payments as outlier payments ($20 million increase), and a -0.1 percent decrease in CY 2019 payments due to the new rural add-on policy mandated by the BBA of 2018 ($20 million decrease).

b. HH PPS for CY 2020 (PDGM)

In conclusion, we estimate that Medicare payments to HHAs for CY 2020 will remain the same compared to CY 2019 as a result of the implementation of the PDGM. Section 51001(a) of the BBA of 2018 requires the Secretary to implement the 30-day unit of payment in a budget-neutral manner.

2. OASIS Changes Related to the HH QRP and HH PPS (PDGM) for CY 2020

In conclusion, we estimate that the changes to OASIS item collection as a result of the proposed changes to the HH QRP and the proposed changes to the HH PPS (PDGM), both effective on and after January 1, 2020, would result in a net $60 million in annualized cost savings, discounted at 7 percent relative to year 2016, over a perpetual time horizon beginning in CY 2020.

3. HHVBP Model

In conclusion, we estimate there would be no net impact (to include either a net increase or reduction in payments) in this proposed rule in Medicare payments to HHAs competing in the HHVBP Model for CY 2019. However, the overall economic impact of the HHVBP Model is an estimated $378 million in total savings from a reduction in unnecessary hospitalizations and SNF usage as a result of greater quality improvements in the home health industry over the

life of the HHVBP Model. We do not believe the changes proposed in this rule would affect the prior estimates.

4. Home Infusion Therapy

a. Health and Safety Standards

In summary, the proposed health and safety standards would not have any economic impact on home infusion therapy suppliers or accreditation organizations.

b. Payment

In conclusion, we estimate that the net impact of the temporary transitional payment to eligible home infusion suppliers for items and services associated with the furnishing of transitional home infusion drugs would result in approximately $60 million in additional Medicare payments to home infusion suppliers in CY 2019.

c. Accreditation of Qualified Home Infusion Therapy Suppliers

In summary, AOs that accredit HIT suppliers must become accredited by an AO designated by the Secretary. In these options, we have attempted to minimize the burden of accreditation on HIT suppliers, which include approving AOs that consider the unique needs of small HIT suppliers. Also, it is likely that the surveys of HIT suppliers will be performed as a desk review instead of an onsite survey. Doing a desk audit survey would prevent the travel time and cost that is required when the AO has to send a survey team to the HIT supplier's location to perform an onsite survey.

This analysis, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis.

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

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 484

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

42 CFR Part 486

Grant programs-health, Health facilities, Medicare, Reporting and recordkeeping requirements, X-rays.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

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

PART 409—HOSPITAL INSURANCE BENEFITS

1. The authority citation for part 409 continues to read as follows:

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

§409.43 [Amended]

2. Section 409.43 is amended --

a. By removing paragraph (c)(2);

b. By resignating paragraphs (c)(3) and (4) as paragraphs (c)(2) and (3);

c. In newly redesignated paragraph (c)(2)(ii) by removing the phrase "for services is submitted for the final percentage prospective payment" and adding in its place the phrase "(for episodes beginning on or before December 31, 2019) or 30-day period (for periods beginning on or after January 1, 2020) is submitted"; and

d. In paragraph (e)(1)(iii) by removing the phrase "during the 60-day episode" and adding in its place the phrase "within 60 days".

3. Section 409.46 is amended by adding paragraph (e) to read as follows:

§409.46 Allowable administrative costs.

* * * * *

(e) Remote patient monitoring. Remote patient monitoring is defined as the collection of physiologic data (for example, ECG, blood pressure, or glucose monitoring) digitally stored and transmitted by the patient or caregiver or both to the home health agency. If remote patient monitoring is used by the home health agency to augment the care planning process, the costs

of the equipment and service related to this system are allowable administrative costs.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

4. The authority citation for part 424 continues to read as follows:

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

5. Section 424.22 is amended by revising paragraphs (b)(2) and (c) to read as follows:

§424.22 Requirements for home health services.

* * * * *

(b) * * *

(2) Content and basis of recertification. As a condition for payment of home health services under Medicare Part A or Medicare Part B, if there is a continuing need for home health services, a physician must recertify the patient's continued eligibility for the home health benefit as outlined in sections 1814(a)(2)(C) and 1835(a)(2)(A) of the Act, as set forth in paragraph (a)(1) of this section, and as specified in paragraphs (b)(2)(i) and (ii) of this section.

(i) Need for occupational therapy may be the basis for continuing services that were initiated because the individual needed skilled nursing care or physical therapy or speech therapy.

(ii) If a patient's underlying condition or complication requires a registered nurse to ensure that essential non-skilled care is achieving its purpose, and necessitates a registered nurse be involved in the development, management, and evaluation of a patient's care plan, the physician must include a brief narrative describing the clinical justification of this need. If the narrative--

(A) Is part of the recertification form, then the narrative must be located immediately

prior to the physician's signature.

(B) Exists as an addendum to the recertification form, in addition to the physician's signature on the recertification form, the physician must sign immediately following the narrative in the addendum.

(c) Determining patient eligibility for Medicare home health services. (1) Documentation in the certifying physician's medical records or the acute/post-acute care facility's medical records (if the patient was directly admitted to home health) or both must be used as the basis for certification of the patient's eligibility for home health as described in paragraphs (a)(1) and (b) of this section. Documentation from the HHA may also be used to support the basis for certification of home health eligibility, but only if the following requirements are met:

(i) The documentation from the HHA can be corroborated by other medical record entries in the certifying physician's medical record for the patient or the acute/post-acute care facility's medical record for the patient or both, thereby creating a clinically consistent picture that the patient is eligible for Medicare home health services.

(ii)(A) The certifying physician signs and dates the HHA documentation demonstrating that the documentation from the HHA was considered when certifying patient eligibility for Medicare home health services.

(B) HHA documentation can include, but is not limited to, the patient's plan of care required under §409.43 of this chapter and the initial or comprehensive assessment of the patient required under §484.55 of this chapter.

(2) The documentation must be provided upon request to review entities or CMS or both. If the documentation used as the basis for the certification of eligibility is not sufficient to

demonstrate that the patient is or was eligible to receive services under the Medicare home health benefit, payment is not rendered for home health services provided.

* * * * *

PART 484–HOME HEALTH SERVICES

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

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

7. Section 484.202 is amended by revising the definitions of "Rural area" and "Urban area" to read as follows:

§484.202 Definitions.

* * * * *

Rural area means an area defined in §412.64(b)(1)(ii)(C) of this chapter.

Urban area means an area defined in §412.64(b)(1)(ii)(A) and (B) of this chapter.

8. Section 484.205 is revised to read as follows:

§484.205 Basis of payment.

(a) Method of payment. An HHA receives a national, standardized prospective payment amount for home health services previously paid on a reasonable cost basis (except the osteoporosis drug defined in section 1861(kk) of the Act) as of August 5, 1997. The national, standardized prospective payment is determined in accordance with §484.215.

(b) Unit of payment--(1) Episodes before December 31, 2019. For episodes beginning on or before December 31, 2019, an HHA receives a unit of payment equal to a national, standardized prospective 60-day episode payment amount.

(2) Periods on or after January 1, 2020. For periods beginning on or after January 1,

2020, a HHA receives a unit of payment equal to a national, standardized prospective 30-day payment amount.

(c) OASIS data. A HHA must submit to CMS the OASIS data described at §484.55(b) and (d) in order for CMS to administer the payment rate methodologies described in §§484.215, 484.220, 484. 230, 484.235, and 484.240.

(d) Payment adjustments. The national, standardized prospective payment amount represents payment in full for all costs associated with furnishing home health services and is subject to the following adjustments and additional payments:

(1) A low-utilization payment adjustment (LUPA) of a predetermined per-visit rate as specified in §484.230.

(2) A partial payment adjustment as specified in §484.235.

(3) An outlier payment as specified in §484.240.

(e) Medical review. All payments under this system may be subject to a medical review adjustment reflecting the following:

(1) Beneficiary eligibility.

(2) Medical necessity determinations.

(3) Case-mix group assignment.

(f) Durable medical equipment (DME) and disposable devices. DME provided as a home health service as defined in section 1861(m) of the Act is paid the fee schedule amount. Separate payment is made for "furnishing NPWT using a disposable device," as that term is defined in §484.202, and is not included in the national, standardized prospective payment.

(g) Split percentage payments. Normally, there are two payments (initial and final) paid for an HH PPS unit of payment. The initial payment is made in response to a request for

anticipated payment (RAP) as described in paragraph (h) of this section, and the residual final payment is made in response to the submission of a final claim. Split percentage payments are made in accordance with requirements at §409.43(c) of this chapter.

(1) Split percentage payments for episodes beginning on or before December 31, 2019--(i) Initial and residual final payments for initial episodes on or before December 31, 2019. (A) The initial payment for initial episodes is paid to an HHA at 60 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for initial episodes is paid at 40 percent of the case-mix and wage-adjusted 60-day episode rate.

(ii) Initial and residual final payments for subsequent episodes before December 31, 2019. (A) The initial payment for subsequent episodes is paid to an HHA at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(B) The residual final payment for subsequent episodes is paid at 50 percent of the case-mix and wage-adjusted 60-day episode rate.

(2) Split percentage payments for periods beginning on or after January 1, 2020--(i) Initial and residual final payments for initial periods beginning on or after January 1, 2020. (A) The initial payment for initial 30-day periods is paid to an HHA at 60 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for initial 30-day periods is paid at 40 percent of the case-mix and wage-adjusted 30-day payment rate.

(ii) Initial and residual final payments for subsequent periods beginning on or after January 1, 2020. (A) The initial payment for subsequent 30-day periods is paid to an HHA at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

(B) The residual final payment for subsequent 30-day periods is paid at 50 percent of the case-mix and wage-adjusted 30-day payment rate.

(iii) Split percentage payments on or after January 1, 2019. Split percentage payments are not made to HHAs that are certified for participation in Medicare effective on or after January 1, 2019. An HHA that is certified for participation in Medicare effective on or after January 1, 2019 receives a single payment for a 30-day period of care after the final claim is submitted.

(h) Requests for anticipated payment (RAP). (1) HHAs that are certified for participation in Medicare effective by December 31, 2018 submit requests for anticipated payment (RAPs) to request the initial split percentage payment as specified in paragraph (g) of this section. HHAs that are certified for participation in Medicare effective on or after January 1, 2019 are still required to submit RAPs although no split percentage payments are made in response to these RAP submissions. The HHA can submit a RAP when all of the following conditions are met:

(i) After the OASIS assessment required at §484.55(b)(1) and (d) is complete, locked or export ready, or there is an agency-wide internal policy establishing the OASIS data is finalized for transmission to the national assessment system.

(ii) Once a physician's verbal orders for home care have been received and documented as required at §§484.60(b) and 409.43(d) of this chapter.

(iii) A plan of care has been established and sent to the physician as required at §409.43(c) of this chapter.

(iv) The first service visit under that plan has been delivered.

(2) A RAP is based on the physician signature requirements in §409.43(c) of this

chapter and is not a Medicare claim for purposes of the Act (although it is a "claim" for purposes of Federal, civil, criminal, and administrative law enforcement authorities, including but not limited to the following:

(i) Civil Monetary Penalties Law (as defined in 42 U.S.C. 1320a-7a (i) (2)).

(ii) The Civil False Claims Act (as defined in 31 U.S.C. 3729(c)).

(iii) The Criminal False Claims Act (18 U.S.C. 287)).

(iv) The RAP is canceled and recovered unless the claim is submitted within the greater of 60 days from the end date of the appropriate unit of payment, as defined in paragraph (b) of this section, or 60 days from the issuance of the RAP.

(3) CMS has the authority to reduce, disprove, or cancel a RAP in situations when protecting Medicare program integrity warrants this action.

§484.210 [Removed and Reserved]

9. Section 484.210 is removed and reserved.

10. Section 484.215 is amended--

a. By revising the section heading;

b. In paragraph (d) introductory text by removing the phrase "CMS calculates the" and adding in its place the phrase "For episodes beginning on or before December 31, 2019, CMS calculates the"; and

c. By adding paragraph (f).

The revisions and addition reads as follows:

§484.215 Initial establishment of the calculation of the national, standardized prospective payment rates.

* * * * *

(f) For periods beginning on or after January 1, 2020, a national, standardized prospective 30-day payment rate applies. The national, standardized prospective 30-day payment rate is an amount determined by the Secretary, as subsequently adjusted in accordance with §484.225.

11. Section 484.220 is amended--

a. By revising the section heading and introductory text; and

b. In paragraph (a) introductory text by removing the phrase "national prospective 60-day episode" and adding in its place the phrase "national, standardized prospective".

The revisions read as follows:

§484.220 Calculation of the case-mix and wage area adjusted prospective payment rates.

CMS adjusts the national, standardized prospective payment rates as referenced in §484.215 to account for the following:

* * * * *

12. Section 484.225 is amended --

a. By revising the section heading and paragraph (a);

b. In paragraphs (b) and (c) by removing the phrase "national prospective 60-day episode" and adding in its place the phrase "national, standardized prospective"; and

c. By adding paragraph (d).

The revisions and addition reads as follows:

§484.225 Annual update of the unadjusted national, standardized prospective payment rates.

(a) CMS annually updates the unadjusted national, standardized prospective payment rate on a calendar year basis (in accordance with section 1895(b)(1)(B) of the Act).

* * * * *

(d) For CY 2020, the national, standardized prospective 30-day payment amount is an amount determined by the Secretary. CMS annually updates this amount on a calendar year basis in accordance with paragraphs (a) through (c) of this section.

13. Section 484.230 is revised to read as follows:

§ 484.230 Low-utilization payment adjustments.

(a) For episodes beginning on or before December 31, 2019, an episode with four or fewer visits is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(1) The national per-visit amount is adjusted by the appropriate wage index based on the site of service of the beneficiary.

(2) An amount is added to the low-utilization payment adjustments for low-utilization episodes that occur as the beneficiary's only episode or initial episode in a sequence of adjacent episodes.

(3) For purposes of the home health PPS, a sequence of adjacent episodes for a beneficiary is a series of claims with no more than 60 days without home care between the end of one episode, which is the 60th day (except for episodes that have been PEP-adjusted), and the beginning of the next episode.

(b) For periods beginning on or after January 1, 2020, an HHA receives a national 30-day payment of a predetermined rate for home health services, unless CMS determines at the end of the 30-day period that the HHA furnished minimal services to a patient during the 30-day period.

(1) For each payment group used to case-mix adjust the 30-day payment rate, the 10th percentile value of total visits during a 30-day period of care is used to create payment group specific thresholds with a minimum threshold of at least 2 visits for each case-mix group.

(2) A 30-day period with a total number of visits less than the threshold is paid the national per-visit amount by discipline determined in accordance with § 484.215(a) and updated annually by the applicable market basket for each visit type, in accordance with § 484.225.

(3) The national per-visit amount is adjusted by the appropriate wage index based on the site of service for the beneficiary.

(c) An amount is added to low-utilization payment adjustments for low-utilization periods that occur as the beneficiary's only 30-day period or initial 30-day period in a sequence of adjacent periods of care. For purposes of the home health PPS, a sequence of adjacent periods of care for a beneficiary is a series of claims with no more than 60 days without home care between the end of one period, which is the 30th day (except for episodes that have been partial payment adjusted), and the beginning of the next episode.

14. Section 484.235 is revised to read as follows:

§ 484.235 Partial payment adjustments.

(a) Partial episode payments (PEPs) for episodes beginning on or before December 31, 2019. (1) An HHA receives a national, standardized 60-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 60-day episode, warrants a new 60-day episode for purposes of payment. A start of care OASIS assessment and physician certification of the new plan of care are required.

(2) The PEP adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 60-day episode.

(ii) The common ownership exception to the transfer PEP adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 60-day episode before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 60-day payment and a new physician certification and a new plan of care, the initial HHA receives a partial episode payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The PEP is calculated by determining the actual days served as a proportion of 60 multiplied by the initial 60-day payment amount.

(b) Partial payment adjustments for periods beginning on or after January 1, 2020. (1) An HHA receives a national, standardized 30-day payment of a predetermined rate for home health services unless CMS determines an intervening event, defined as a beneficiary elected transfer or discharge with goals met or no expectation of return to home health and the beneficiary returned to home health during the 30-day period, warrants a new 30-day period for purposes of payment. A start of care OASIS assessment and physician certification of the new

plan of care are required.

(2) The partial payment adjustment does not apply in situations of transfers among HHAs of common ownership.

(i) Those situations are considered services provided under arrangement on behalf of the originating HHA by the receiving HHA with the common ownership interest for the balance of the 30-day period.

(ii) The common ownership exception to the transfer partial payment adjustment does not apply if the beneficiary moves to a different MSA or Non-MSA during the 30-day period before the transfer to the receiving HHA.

(iii) The transferring HHA in situations of common ownership not only serves as a billing agent, but must also exercise professional responsibility over the arranged-for services in order for services provided under arrangements to be paid.

(3) If the intervening event warrants a new 30-day payment and a new physician certification and a new plan of care, the initial HHA receives a partial payment adjustment reflecting the length of time the patient remained under its care based on the first billable visit date through and including the last billable visit date. The partial payment is calculated by determining the actual days served as a proportion of 30 multiplied by the initial 30-day payment amount.

15. Section 484.240 is revised to read as follows:

§ 484.240 Outlier payments.

(a) For episodes beginning on or before December 31, 2019, an HHA receives an outlier payment for an episode whose estimated costs exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the episode payment amount for

that group, or the PEP adjustment amount for the episode, plus a fixed dollar loss amount that is the same for all case-mix groups.

(b) For periods beginning on or after January 1, 2020, an HHA receives an outlier payment for a 30-day period whose estimated cost exceeds a threshold amount for each case-mix group. The outlier threshold for each case-mix group is the 30-day payment amount for that group, or the partial payment adjustment amount for the 30-day period, plus a fixed dollar loss amount that is the same for all case-mix groups.

(c) The outlier payment is a proportion of the amount of imputed cost beyond the threshold.

(d) CMS imputes the cost for each claim by multiplying the national per-15 minute unit amount of each discipline by the number of 15 minute units in the discipline and computing the total imputed cost for all disciplines.

16. Section 484.250 is amended by revising paragraph (a)(1) to read as follows:

§ 484.250 Patient assessment data.

(a) * * *

(1) Such OASIS data described at §484.55(b) and (d) as is necessary for CMS to administer the payment rate methodologies described in §§ 484.215, 484.220, 484.230, 484.235, and 484.240; and such OASIS data described at §484.55(b) and (d) as is necessary to meet the quality reporting requirements of section 1895(b)(3)(B)(v) of the Act.

* * * * *

17. Section 484.320 is amended by revising paragraph (c) to read as follows:

§484.320 Calculation of the Total Performance Score.

* * * * *

(c)(1) For performance years 1 through 3, CMS will sum all points awarded for each applicable measure excluding the New Measures, weighted equally at the individual measure level to calculate a value worth 90 percent of the Total Performance Score.

(2) For performance years 4 and 5, CMS will sum all points awarded for each applicable measure within each category of measures (OASIS-based, claims-based and HHCAHPs) excluding the New Measures, weighted at 35 percent for the OASIS-based measure category, 35 percent for the claims-based measure category, and 30 percent for the HHCAHPS measure category when all three measure categories are reported, to calculate a value worth 90 percent of the Total Performance Score.

* * * * *

PART 486—CONDITIONS FOR COVERAGE OF SPECIALIZED SERVICES FURNISHED BY SUPPLIERS

18. The authority citation for part 486 is revised to read as follows:

Authority: 42 U.S.C. 1302, and 1395hh.

19. Add reserved subpart H and subpart I to read as follows:

Subpart H [Reserved]

Subpart I--Requirements for Home Infusion Therapy Suppliers

General Provisions

Sec.

Standards for Home Infusion Therapy

Subpart I--Requirements for Home Infusion Therapy Suppliers

General Provisions

§486.500 Basis and scope.

Section 1861(s)(2)(iii) of the Act requires the Secretary to establish the conditions that home infusion therapy suppliers must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients.

§486.505 Definitions.

Applicable provider means a physician, a nurse provider, and a physician assistant.

Home means a place of residence used as the home of an individual, including an institution that is used as a home. An institution that is used as a home may not be a hospital, CAH, or SNF as defined in section 1861(e)(1), 1861(mm)(1), or 1819(a)(1) of the Act, respectively.

Home infusion drug means a parental drug or biological administered intravenously, or subcutaneously for an administration period of 15 minutes or more, in the home of an individual through a pump that is an item of durable medical equipment. The term does not include insulin pump systems or a self-administered drug or biological on a self-administered drug exclusion list.

Infusion drug administration calendar day means the day on which home infusion therapy services are furnished by skilled professionals in the individual's home on the day of

infusion drug administration. The skilled services provided on such day must be so inherently complex that they can only be safely and effectively performed by, or under the supervision of, professional or technical personnel

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets the all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Meets such other requirements as the Secretary determines appropriate.

Standards for Home Infusion Therapy

§486.520 Plan of care.

The qualified home infusion therapy supplier ensures the following:

(a) All patients must be under the care of an applicable provider.

(b) All patients must have a plan of care established by a physician that prescribes the type, amount, and duration of the home infusion therapy services that are to be furnished.

(c) The plan of care for each patient must be periodically reviewed by the physician.

§486.525 Required services.

The qualified home infusion therapy supplier must provide the following services on a 7-day-a-week, 24-hour-a-day basis in accordance with the plan of care:

(a) Professional services, including nursing services.

(b) Patient training and education not otherwise paid for as durable medical equipment as described in §424.57(c)(12) of this chapter.

(c) Remote monitoring and monitoring services for the provision of home infusion therapy services and home infusion drugs.

PART 488 – SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

20. The authority citation for part 488 is revised to read as follows:

Authority: 42 U.S.C 1302, and 1395hh.

21. Section 488.5 is amended--

a. By redesignating paragraphs (a)(7) through (21) as paragraphs (a)(8) through (22);

b. By adding a new paragraph (a)(7);

c. In newly redesignated paragraph (a)(18)(i) by removing the word "and" at the end of the paragraph;

d. In newly redesignated paragraph (a)(18)(ii) by removing the period and adding in its place "; and"; and

e. By adding paragraph (a)(18)(iii).

The additions read as follows:

§488.5 Application and re-application procedures for national accrediting organizations.

(a) * * *

(7) A statement acknowledging that all accrediting organization surveyors have completed or will complete the relevant program specific CMS online trainings established for state surveyors, initially, and thereafter.

* * * * *

(18) * * *

(iii) Include a written statement that if a fully accredited and deemed facility in good standing provides written notification that they wish to voluntarily withdraw from the accrediting organization's CMS-approved accreditation program, the accrediting organization must continue the facility's current accreditation in full force and effect until the effective date of withdrawal identified by the facility or the expiration date of the term of accreditation, whichever comes first.

* * * * *

22. Add reserved subpart K and subpart L to read as follows:

Subpart K [Reserved]

Subpart L--Accreditation of Home Infusion Therapy Suppliers

General Provisions

Sec.

Subpart L--Accreditation of Home Infusion Therapy Suppliers

General Provisions

§488.1000 Basis and scope.

(a) Regulatory basis for home infusion therapy services. The home infusion therapy health and safety regulations are codified at part 486, subpart L, of this chapter.

(b) Statutory basis for the accreditation of home infusion therapy suppliers. (1) Sections 1102 and 1871 of the Act require that the Secretary prescribe such regulations as may be necessary to carry out the administration of the Medicare program.

(2) Section 1834(u)(5) of the Act require the Secretary to designate and approve independent organizations for the purposes of accrediting qualified home infusion therapy suppliers.

(c) Scope. This subpart sets forth the following:

(1) Application and reapplication procedures for national accrediting organizations seeking approval or re-approval of authority to accredit qualified home infusion therapy suppliers.

(2) Ongoing CMS oversight processes for approved accrediting organizations that accredit qualified home infusion therapy suppliers.

(3) Appeal procedures for accrediting organizations that accredit qualified home infusion therapy suppliers.

§488.1005 Definitions.

As used in this subpart--

Immediate jeopardy means a situation in which the provider's or supplier's non-compliance with one or more Medicare accreditation requirements has caused, or is likely to cause, serious injury, harm, impairment, or death to a patient.

National accrediting organization means an organization that accredits provider or supplier entities under a specific program and whose accredited provider or supplier entities under each program are widely dispersed geographically across the United States. In addition, the specific program is active, fully implemented, and operational.

National in scope means a program is fully implemented, operational, and widely dispersed geographically throughout the country.

Qualified home infusion therapy supplier means a supplier of home infusion therapy that meets the all of the following criteria which are set forth at section 1861(iii)(3)(D)(i) of the Act:

(1) Furnishes infusion therapy to individuals with acute or chronic conditions requiring administration of home infusion drugs.

(2) Ensures the safe and effective provision and administration of home infusion therapy on a 7-day-a-week, 24-hour-a-day basis.

(3) Is accredited by an organization designated by the Secretary in accordance with section 1834(u)(5) of the Act.

(4) Meets such other requirements as the Secretary determines appropriate.

Reasonable assurance means an accrediting organization has demonstrated to CMS' satisfaction that its accreditation program requirements meet or exceed the Medicare program requirements.

Rural area as defined at section 1886(d)(2)(D) of the Act.

Substantial allegation of non-compliance means a complaint from any of a variety of sources (such as patient, relative, or third party), including complaints submitted in person, by telephone, through written correspondence, or in the newspaper, magazine articles or other media, that would, if found to be present, adversely affect the health and safety of patients and raises doubts as to a qualified home infusion therapy supplier's compliance with the applicable Medicare accreditation requirements.

Approval and Oversight of Home Infusion Therapy Supplier Accrediting Organizations

§488.1010 Application and reapplication procedures for national accrediting organizations.

(a) Information submitted with application. A national home infusion therapy accrediting organization applying to CMS for approval or re-approval of a designated home infusion therapy accreditation program must furnish CMS with information and materials that demonstrate that its home infusion therapy accreditation program requirements meet or exceed the applicable Medicare requirements for accrediting organizations, including the following:

(1) Documentation that demonstrates the organization meets the definition of a national accrediting organization under §488.1005 as it relates to the accreditation program.

(2) The Medicare provider or supplier type for which the organization is requesting approval or re-approval.

(3) Documentation that demonstrates the home infusion therapy accrediting

organization's ability to take into account the capacities of rural home infusion therapy suppliers (as required by section 1834(u)(5)(A)(ii) of the Act).

(4) Information that demonstrates the home infusion therapy accrediting organization's knowledge, expertise, and experience in home infusion therapy.

(5) A detailed crosswalk (in table format) that identifies, for each of the applicable Medicare requirements, the exact language of the organization's comparable accreditation requirements and standards.

(6) A detailed description of the home infusion therapy accrediting organization's survey processes to confirm that a home infusion therapy supplier's processes are comparable to those of Medicare. This description must include all of the following:

(i) The types and frequency of surveys performed, and a rationale for which accreditation requirements will be evaluated via onsite surveys and which will be evaluated via offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements, including an explanation of how the accrediting organization will maintain the schedule it proposes.

(ii) Copies of the home infusion therapy accrediting organizations survey and audit forms, guidelines, and instructions to surveyors.

(iii) Documentation demonstrating that the home infusion therapy accrediting organization's onsite survey or offsite audit reports identify, for each finding of non-compliance with accreditation standards, the comparable Medicare home infusion therapy accreditation requirements, as applicable.

(iv) A description of the home infusion therapy accrediting organization's accreditation survey review process.

(v) A description of the home infusion therapy accrediting organization's procedures and timelines for notifying a surveyed or audited home infusion therapy supplier of non-compliance with the home infusion therapy accreditation program's standards.

(vi) A description of the home infusion therapy accrediting organization's procedures and timelines for monitoring the home infusion therapy supplier's correction of identified non-compliance with the accreditation program's standards.

(vii) The ability of the home infusion therapy accrediting organization to conduct timely reviews of accreditation applications.

(viii) A statement acknowledging that, as a condition for CMS approval of a national accrediting organization's accreditation program, the home infusion therapy accrediting organization agrees to provide CMS with information extracted from each home infusion therapy accreditation onsite survey, offsite audit or other evaluation strategies as part of its data submissions required under paragraph (a)(19) of this section, and, upon request from CMS, a copy of the most recent accreditation onsite survey, offsite audit, or other evaluation strategy together with any other information related to the survey as CMS may require (including corrective action plans).

(ix) A statement acknowledging that the home infusion therapy accrediting organization will provide timely notification to CMS when an accreditation survey or complaint investigation identifies an immediate jeopardy as that term is defined at §488.1005. Using the format specified by CMS, the home infusion therapy accrediting organization must notify CMS within 2 business days from the date the accrediting organization identifies the immediate jeopardy.

(7) Procedures to ensure that--

(i) Unannounced onsite surveys, as appropriate, will be conducted periodically, including procedures that protect against unannounced surveys becoming known to the provider or supplier in advance of the visit; or

(ii) Offsite survey audits are performed to evaluate the quality of services provided which may be followed up with periodic onsite visits.

(8) The criteria for determining the size and composition of the home infusion therapy accrediting organization's survey, audit and other evaluation strategy teams for individual supplier onsite surveys. The home infusion therapy accrediting organization's criteria should include, but not be limited to the following information:

(i) The expected number of individual home infusion therapy supplier locations to be surveyed using an onsite survey.

(ii) The number of home infusion therapy suppliers to be surveyed using off-site audits.

(iii) A description of other types of home infusion therapy accreditation review activities to be used.

(iv) The reasons for each type of survey (that is, initial accreditation survey, reaccreditation survey, and complaint survey).

(9) The overall adequacy of the number of the home infusion therapy accrediting organization's surveyors, auditors, and other staff available to perform survey related activities, including how the organization will increase the size of the survey, audit, and other evaluation staff to match growth in the number of accredited facilities or programs while maintaining re-accreditation intervals for existing accredited facilities or programs.

(10) Detailed information about the individuals who perform onsite surveys, offsite audits or other strategies for ensuring accredited home infusion therapy suppliers maintain

adherence to the home infusion therapy accreditation program requirements, including all of the following information:

(i) The number and types of professional and technical staff available for conducting onsite surveys, offsite audits, or other strategies for ensuring accredited home infusion therapy suppliers maintain adherence to the home infusion therapy accreditation program requirements.

(ii) The education, employment, and experience requirements surveyors and auditors must meet.

(iii) The content and length of the orientation program.

(11) The content, frequency and types of in-service training provided to survey and audit personnel.

(12) The evaluation systems used to monitor the performance of individual surveyors, auditors and survey teams.

(13) The home infusion therapy accrediting organization's policies and procedures to avoid conflicts of interest, including the appearance of conflicts of interest, involving individuals who conduct surveys, audits or participate in accreditation decisions.

(14) The policies and procedures used when a home infusion therapy supplier has a dispute regarding survey or audit findings, or an adverse decision.

(15) Procedures for the home infusion therapy supplier to use to notify the home infusion therapy accrediting organization when the accredited home infusion therapy supplier does the either of the following:

(i) Removes or ceases furnishing services for which they are accredited.

(ii) Adds services for which they are not accredited.

(16) The home infusion therapy accrediting organization's procedures for responding

to, and investigating complaints against accredited facilities, including policies and procedures regarding referrals, when applicable, to appropriate licensing bodies, ombudsmen offices, and CMS.

(17) A description of the home infusion therapy accrediting organization's accreditation status decision-making process. The home infusion therapy accrediting organization must furnish the following:

(i) Its process for addressing deficiencies identified with accreditation program requirements, and the procedures used to monitor the correction of deficiencies identified during an accreditation survey and audit process.

(ii) A description of all types and categories of accreditation decisions associated with the program, including the duration of each of the organization's accreditation decisions.

(iii) Its policies and procedures for the granting, withholding or removal of accreditation status for facilities that fail to meet the accrediting organization's standards or requirements, assignment of less than full accreditation status or other actions taken by the organization in response to non-compliance with its standards and requirements.

(iv) A statement acknowledging that the home infusion therapy accrediting organization agrees to notify CMS (in a manner CMS specifies) of any decision to revoke, terminate, or revise the accreditation status of a home infusion therapy supplier, within 3 business days from the date the organization takes an action.

(18) A list of all currently accredited home infusion therapy suppliers, the type and category of accreditation, currently held by each, and the expiration date for each home infusion therapy supplier's current accreditation.

(19) A schedule of all survey activity (such as onsite surveys, offsite audits and other

types if survey strategies) expected to be conducted by the organization during the 6-month period following submission of an initial or renewal application.

(20) A written presentation that demonstrates the organization's ability to furnish CMS with electronic data.

(21) A description of the home infusion therapy accrediting organization's data management and analysis system with respect to its surveys and accreditation decisions, including all of the following:

(i) A detailed description of how the home infusion therapy accrediting organization uses its data to assure the compliance of its home infusion therapy accreditation program with the Medicare home infusion therapy accreditation program requirements.

(ii) A written statement acknowledging that the home infusion therapy accrediting organization agrees to submit timely, accurate, and complete data that CMS has determined is both necessary to evaluate the accrediting organization's performance and is not unduly burdensome for the accrediting organization to submit.

(A) The organization must submit necessary data according to the instructions and timeframes CMS specifies.

(B) Data to be submitted includes the following:

(1) Accredited home infusion therapy supplier identifying information.

(2) Survey findings.

(3) Quality measures.

(4) Notices of accreditation decisions.

(22) The three most recent annual audited financial statements of the home infusion therapy accrediting organization that demonstrate that the organization's staffing, funding, and

other resources are adequate to perform the required surveys, audits, and related activities to maintain the accreditation program.

(23) A written statement acknowledging that, as a condition for approval, the home infusion therapy accrediting organization agrees to the following:

(i) Voluntary termination. Provide written notification to CMS and all home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program at least 90 calendar days in advance of the effective date of a decision by the home infusion therapy accrediting organization to voluntarily terminate its CMS-approved home infusion therapy accreditation program and the implications for the suppliers' payment status once their current term of accreditation expires in accordance with the requirements at §488.1045(a).

(ii) Involuntary termination. Provide written notification to all accredited home infusion therapy suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of its accreditation program and the implications for the home infusion therapy supplier's payment status in accordance with the requirements at §488.1045(b) once their current term of accreditation expires.

(A) For both voluntary and involuntary terminations, provide a second written notification to all accredited home infusion therapy suppliers 10 calendar days prior to the organization's accreditation program effective date of termination.

(B) Notify CMS, in writing (electronically or hard copy), within 2 business days of a deficiency identified in any accredited home infusion therapy supplier from any source where the deficiency poses an immediate jeopardy to the home infusion therapy supplier's

beneficiaries or a hazard to the general public.

(iii) Provide, on an annual basis, summary accreditation activity data and trends including the following:

(A) Deficiencies.

(B) Complaints.

(C) Terminations.

(D) Withdrawals.

(E) Denials.

(F) Accreditation decisions.

(G) Other survey-related activities as specified by CMS.

(iv) If CMS terminates a home infusion therapy accrediting organization's approved status, the home infusion therapy accrediting organization must work collaboratively with CMS to direct its accredited home infusion therapy suppliers to the remaining CMS-approved accrediting organizations within a reasonable period of time.

(v) Notify CMS at least 60 days in advance of the implementation date of any significant proposed changes in its CMS-approved home infusion therapy accreditation program and that it agrees not to implement the proposed changes without prior written notice of continued program approval from CMS, except as provided for at §488.1040(b)(2).

(vi) A statement acknowledging that, in response to a written notice from CMS to the home infusion therapy accrediting organization of a change in the applicable home infusion therapy accreditation requirements or survey process, the organization will provide CMS with proposed corresponding changes in the accrediting organization's home infusion therapy accreditation requirements for its CMS-approved home infusion therapy accreditation program

to ensure that its accreditation standards continue to meet or exceed those of Medicare, or survey process remains comparable with that of Medicare. The home infusion therapy accrediting organization must comply with the following requirements:

(A) The proposed changes must be submitted within 30 calendar days of the date of the written CMS notice to the home infusion therapy accrediting organization or by a date specified in the notice, whichever is later. CMS gives due consideration to a home infusion therapy accrediting organization's request for an extension of the deadline as long as it is submitted prior to the due date.

(B) The proposed changes are not to be implemented without prior written notice of continued program approval from CMS, except as provided for at §488.1040(b)(2)(ii).

(24) The organization's proposed fees for accreditation, including any plans for reducing the burden and cost of accreditation to small and rural suppliers.

(b) Additional information needed. If CMS determines that additional information is necessary to make a determination for approval or denial of the home infusion therapy accrediting organization's initial application or re-application for CMS-approval of an accreditation program, CMS requires that the home infusion therapy accrediting organization s submit any specific documentation requirements and attestations as a condition of approval of accreditation status. CMS notifies the home infusion therapy accrediting organization and afford it an opportunity to provide the additional information.

(c) Withdrawing an application. A home infusion therapy accrediting organization may withdraw its initial application for CMS' approval of its home infusion therapy accreditation program at any time before CMS publishes the final notice described in §488.1025(b).

(d) Notice of approval or disapproval of application. CMS sends a notice of its

decision to approve or disapprove the home infusion therapy accrediting organization's application within 210 calendar days from the date CMS determines the home infusion therapy accrediting organization's application is complete. The final notice specifies the following:

(1) The basis for the decision.

(2) The effective date.

(3) The term of the approval (not exceed 6 years).

§488.1015 Resubmitting a request for reapproval.

(a) Except as provided in paragraph (b) of this section, a home infusion therapy accrediting organization whose request for CMS's approval or re-approval of an accreditation program has been denied, or a home infusion therapy accrediting organization that has voluntarily withdrawn an initial application, may resubmit its application if the home infusion therapy accrediting organization satisfies all of the following requirements:

(1) Revises its home infusion therapy accreditation program to address the issues related to the denial of its previous request or its voluntary withdrawal.

(2) Resubmits the application in its entirety.

(b) If a home infusion therapy accrediting organization has requested, in accordance with §488.1050, a reconsideration of CMS's disapproval, it may not submit a new application for approval of a home infusion therapy accreditation program until such reconsideration is administratively final.

§488.1020 Public notice and comment.

CMS publishes a notice in the **Federal Register** when the following conditions are met:

(a) Proposed notice. CMS publishes a notice after the receipt of a completed application from a national home infusion therapy accrediting organization seeking CMS's

approval of a home infusion therapy accreditation program. The notice identifies the home infusion therapy accrediting organization, the type of suppliers covered by the home infusion therapy accreditation program, and provides at least a 30 day public comment period (beginning on the date of publication).

(b) Final notice. The final notice announces CMS decision to approve or deny a national accrediting organization application. The notice specifies the basis for the CMS decision.

(1) Approval or re-approval. If CMS approves or re-approves the home infusion therapy accrediting organization's home infusion therapy accreditation program, the final notice at a minimum includes the following information:

(i) A description of how the home infusion therapy accreditation program meets or exceeds Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of approval (no later than the publication date of the notice).

(iii) The term of the approval (6 years or less).

(2) Denial. If CMS does not approve the home infusion therapy accrediting organization's accreditation program, the final notice describes the following:

(i) How the home infusion therapy accrediting organization fails to meet Medicare home infusion therapy accreditation program requirements.

(ii) The effective date of the decision.

§488.1025 Release and use of home infusion therapy accreditation surveys.

The home infusion therapy accrediting organization must include, in its accreditation agreement with each supplier, an acknowledgement that the supplier agrees to release to CMS a copy of its most current accreditation survey and any information related to the survey that

CMS may require, corrective action plans.

(a) CMS may determine that a home infusion therapy supplier does not meet the applicable Medicare conditions or requirements on the basis of its own investigation of the accreditation survey or any other information related to the survey.

(b) With the exception of home health agency surveys, general disclosure of an accrediting organization's survey information is prohibited under section 1865(b) of the Act. CMS may publically disclose an accreditation survey and information related to the survey, upon written request, to the extent that the accreditation survey and survey information are related to an enforcement action taken by CMS.

§488.1030 Ongoing review of home infusion therapy accrediting organizations.

(a) Performance review. CMS evaluates the performance of each CMS-approved home infusion therapy accreditation program on an ongoing basis. This review includes the review of the following:

(1) The home infusion therapy accrediting organization's survey activity.

(2) The home infusion therapy accrediting organization's continued fulfillment of the requirements at §§488.1010 and 488.1035.

(b) Comparability review. CMS assesses the equivalency of a home infusion therapy accrediting organization's CMS-approved program requirements with the comparable Medicare home infusion therapy accreditation requirements after CMS imposes new or revised Medicare accreditation requirements. When this occurs, the following takes place:

(1) CMS provides the home infusion therapy accrediting organizations with written notice of the changes to the to the Medicare home infusion therapy accreditation requirements.

(2) The home infusion therapy accrediting organization must make revisions to its home

infusion therapy accreditation standards or survey processes which incorporate the new or revised Medicare accreditation requirements.

(3) In the written notice, CMS specifies the deadline (no less than 30 calendar days) by which the home infusion therapy accrediting organization must submit its proposed revised home infusion therapy accreditation standard or survey process revisions, and the timeframe(s) for implementation of these revised home infusion therapy accreditation standards.

(4) CMS may extend the submission deadline by which the accrediting organization must submit its proposed revised home infusion therapy accreditation standards and survey processes, if both of the following occur:

(i) The accrediting organization submits a written request for an extension of the submission deadline.

(ii) The request for extension is submitted prior to the original submission deadline.

(5) After completing the comparability review of the home infusion therapy accrediting organizations revised home infusion therapy accreditation standards and survey processes, CMS shall provide written notification to the home infusion therapy accrediting organization regarding whether or not its home infusion therapy accreditation program, including the proposed revised home infusion therapy accreditation standards and implementation timeframe(s), continues to meet or exceed all applicable Medicare requirements.

(6) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide the written notice to the home infusion therapy accrediting organization required, then the revised home infusion therapy accreditation standards and program is deemed to meet or exceed all applicable Medicare requirements and to have continued CMS-approval.

(7) If a home infusion therapy accrediting organization is required to submit a new application because CMS imposes new home infusion therapy regulations or makes significant substantive revisions to the existing home infusion therapy regulations, CMS provides notice of the decision to approve or disapprove the new application submitted by the home infusion therapy accrediting organization within the time period specified in §488.1010(d).

(8) If a home infusion therapy accrediting organization fails to submit its proposed changes to its home infusion therapy accreditation standards and survey processes within the required timeframe, or fails to implement the proposed changes that have been determined or deemed by CMS to be comparable, CMS may open an accreditation program review in accordance with paragraph (d) of this section.

(c) Review of revised home infusion therapy accreditation standards submitted to CMS by an accrediting organization. When a home infusion therapy accrediting organization proposes to adopt new or revised accreditation standards, requirements or changes in its survey process, the home infusion therapy accrediting organization must do the following:

(1) Provide CMS with written notice of any proposed changes in home infusion therapy accreditation standards, requirements or survey process at least 60 days prior to the proposed implementation date of the proposed changes.

(2) Not implement any of the proposed changes before receiving CMS's approval, except as provided in paragraph (c)(4) of this section.

(3) Provide written notice to CMS that includes all of the following:

(i) A detailed description of the changes that are to be made to the organization's home infusion therapy accreditation standards, requirements and survey processes.

(ii) A detailed crosswalk (in table format) that states the exact language of the

organization's revised accreditation requirements and the applicable Medicare requirements for each.

(4) CMS must provide a written notice to the home infusion therapy accrediting organization which states whether the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements within 60 days of receipt of the home infusion therapy accrediting organization's proposed changes. If CMS has made a finding that the home infusion therapy accrediting organization's home infusion therapy accreditation program, accreditation requirements and survey processes, including the proposed revisions does not continue to meet or exceed all applicable Medicare home infusion therapy requirements. CMS must state the reasons for these findings.

(5) If, no later than 60 calendar days after receipt of the home infusion therapy accrediting organization's proposed changes, CMS does not provide written notice to the home infusion therapy accrediting organization that the home infusion therapy accreditation program, including the proposed revisions, continues or does not continue to meet or exceed all applicable Medicare home infusion therapy requirements, then the revised home infusion therapy accreditation program is deemed to meet or exceed all applicable Medicare home infusion therapy requirements and to have continued CMS approval.

(6) If a home infusion therapy accrediting organization implements changes that have neither been determined nor deemed by CMS to be comparable to the applicable Medicare home infusion therapy requirements, CMS may open a home infusion therapy accreditation program review in accordance with paragraph (d) of this section.

(d) CMS-approved home infusion therapy accreditation program review. If a

comparability, performance, or standards review reveals evidence of substantial non-compliance of a home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program with the requirements of this subpart, CMS may initiate a home infusion therapy accreditation program review.

(1) If a home infusion therapy accreditation program review is initiated, CMS will provide written notice to the home infusion therapy accrediting organization indicating that its CMS-approved accreditation program approval may be in jeopardy and that a home infusion therapy accreditation program review is being initiated. The notice will provide all of the following information:

(i) A statement of the instances, rates or patterns of non-compliance identified, as well as other related information, if applicable.

(ii) A description of the process to be followed during the review, including a description of the opportunities for the home infusion therapy accrediting organization to offer factual information related to CMS' findings.

(iii) A description of the possible actions that may be imposed by CMS based on the findings of the home infusion therapy accreditation program review.

(iv) The actions the home infusion therapy accrediting organization must take to address the identified deficiencies

(v) The length of the accreditation program review probation period, which will include monitoring of the home infusion therapy accrediting organization's performance and implementation of the corrective action plan. The probation period is not to exceed 180 calendar days from the date that CMS approves the AOs corrective action plan.

(2) CMS will review and approve the home infusion therapy accrediting organization's

plan of correction for acceptability within 30 days after receipt.

(3) CMS will monitor the AO's performance and implementation of the plan of correction during the probation period which is not to exceed 180 days from the date of approval of the plan of correction.

(4) If CMS determines, as a result of the home infusion therapy accreditation program review or a review of an application for renewal of the accrediting organizations existing CMS-approved home infusion therapy accreditation program, that the home infusion therapy accrediting organization has failed to meet any of the requirements of this subpart, CMS may place the home infusion therapy accrediting organization's CMS-approved home infusion therapy accreditation program on an additional probation period of up to 180 calendar days subsequent to the 180-day probation period described in paragraph (d)(1)(v) of this section to implement additional corrective actions or demonstrate sustained compliance, not to exceed the home infusion therapy accrediting organization's current term of approval. In the case of a renewal application where CMS has already placed the home infusion therapy accreditation program on probation, CMS indicates that any approval of the application is conditional while the program is placed on probation.

(i) Within 60 calendar days after the end of any probationary period, CMS issues a written determination to the home infusion therapy accrediting organization as to whether or not its CMS-approved home infusion therapy accreditation program continues to meet the requirements of this subpart, including the reasons for the determination.

(ii) If CMS determines that the home infusion therapy accrediting organization does not meet the requirements, CMS may withdraw approval of the CMS-approved home infusion therapy accreditation program. The notice of determination provided to the home infusion

therapy accrediting organization includes notice of the removal of approval, reason for the removal, including the effective date determined in accordance with paragraph (d)(4)(iii) of this section.

(iii) CMS publishes in the **Federal Register** a notice of its decision to withdraw approval of a CMS-approved accreditation program, including the reasons for the withdrawal, effective 60 calendar days after the date of publication of the notice.

(e) Immediate jeopardy. If at any time CMS determines that the continued approval of a CMS-approved home infusion therapy accreditation program of any home infusion therapy accrediting organization poses an immediate jeopardy to the patients of the suppliers accredited under the program, or the continued approval otherwise constitutes a significant hazard to the public health, CMS may immediately withdraw the approval of a CMS-approved home infusion therapy accreditation program of that home infusion therapy accrediting organization and publish a notice of the removal, including the reasons for it, in the **Federal Register**.

(f) Notification to home infusion therapy suppliers of withdrawal of CMS approval status. A home infusion therapy accrediting organization whose CMS approval of its home infusion therapy accreditation program has been withdrawn must notify each of its accredited home infusion therapy suppliers, in writing, of the withdrawal of CMS approval status no later than 30 calendar days after the notice is published in the **Federal Register**. The notification to the accredited home infusion therapy suppliers must inform them of the implications for their payment status once their current term of accreditation expires.

§ 488.1035 Ongoing responsibilities of a CMS-approved home infusion therapy accrediting organization.

A home infusion therapy accreditation organization approved by CMS must carry out

the following activities on an ongoing basis:

(a) Provide CMS with all of the following in written format (either electronic or hard copy):

(1) Copies of all home infusion therapy accreditation surveys, together with any survey-related information that CMS may require (including corrective action plans and summaries of findings with respect to unmet CMS requirements).

(2) Notice of all accreditation decisions.

(3) Notice of all complaints related to providers or suppliers.

(4) Information about all home infusion therapy accredited suppliers against which the home infusion therapy accreditation organization has taken remedial or adverse action, including revocation, withdrawal, or revision of the providers or suppliers accreditation.

(5) The home infusion therapy accrediting organization must provide, on an annual basis, summary data specified by CMS that relate to the past year's accreditation activities and trends.

(6) Notice of any proposed changes in the home infusion therapy accrediting organization's accreditation standards or requirements or survey process. If the home infusion therapy accrediting organization implements the changes before or without CMS' approval, CMS may withdraw its approval of the accrediting organization.

(b) Within 30 calendar days after a change in CMS requirements, the home infusion therapy accrediting organization must submit an acknowledgment of receipt of CMS' notification to CMS.

(c) The home infusion therapy accrediting organization must permit its surveyors to serve as witnesses if CMS takes an adverse action based on accreditation findings.

(d) Within 2 business days of identifying a deficiency of an accredited home infusion therapy supplier that poses immediate jeopardy to a beneficiary or to the general public, the home infusion therapy accrediting organization must provide CMS with written notice of the deficiency and any adverse action implemented by the accrediting organization.

(e) Within 10 calendar days after CMS' notice to a CMS-approved home infusion therapy accrediting organization that CMS intends to withdraw approval of the home infusion therapy accrediting organization, the home infusion therapy accrediting organization must provide written notice of the withdrawal to all of the home infusion therapy accrediting organization's accredited suppliers.

§488.1040 Onsite observations of home infusion therapy accrediting organization operations.

(a) As part of the application review process, the ongoing review process, or the continuing oversight of a home infusion therapy accrediting organization's performance, CMS may conduct onsite inspections of the home infusion therapy accrediting organization's operations and offices at any time to verify the home infusion therapy accrediting organization's representations and to assess the home infusion therapy accrediting organization's compliance with its own policies and procedures.

(b) Activities to be performed by CMS staff during the onsite inspections may include, but are not limited to the following:

(1) Interviews with various accrediting organization staff.

(2) Review of documents, survey files, audit tools, and related records.

(3) Observation of meetings concerning the home infusion therapy accreditation process.

(4) Auditing meetings concerning the accreditation process.

(5) Observation of in-progress surveys and audits.

(6) Evaluation of the accrediting organization's survey results and accreditation decision-making process.

§488.1045 Voluntary and involuntary termination.

(a) Voluntary termination by a CMS-approved accrediting program. In accordance with §488.1010(a)(23), a home infusion therapy accrediting organization that decides to voluntarily terminate its CMS-approved home infusion therapy accreditation program must provide written notice at least 90 days in advance of the effective date of the termination to CMS and each of its accredited home infusion therapy suppliers.

(b) Involuntary termination of an accrediting organization's approval by CMS. Once CMS publishes the notice in the **Federal Register** announcing its decision terminate the home infusion therapy accrediting organization's home infusion therapy accreditation program, the home infusion therapy accrediting organization must provide written notification to all suppliers accredited under its CMS-approved home infusion therapy accreditation program no later than 30 calendar days after the notice is published in the **Federal Register** announcing that CMS is withdrawing its approval of its home infusion therapy accreditation program and the implications for the home infusion therapy suppliers payment status in accordance with the requirements at §488.1010(f) once their current term of accreditation expires.

(c) Voluntary and involuntary terminations. For both voluntary and involuntary terminations –

(1) The accreditation status of affected home infusion therapy suppliers is considered to remain in effect until their current term of accreditation expires;

(2) If the home infusion therapy supplier wishes to avoid a suspension of payment, it must provide written notice to CMS at least 60-calendar days prior to its accreditation expiration date that it has submitted an application for home infusion therapy accreditation under another CMS-approved home infusion therapy accreditation program. Failure to comply with this 60-calendar day requirement prior to expiration of their current home infusion therapy accreditation stations within could result in a suspension of payment; and

(3) The home infusion therapy accrediting organization provides a second written notification to all accredited home infusion therapy suppliers ten calendar days prior to the organization's accreditation program effective date of termination.

(d) Voluntary withdrawal from accreditation requested by a home infusion therapy supplier. If a voluntary withdrawal from accreditation is requested by the home infusion therapy supplier, the withdrawal may not become effective until the accrediting organization completes all of the following steps:

(1) The accrediting organization must contact the home infusion therapy supplier to seek written confirmation that the home infusion therapy supplier intends to voluntarily withdraw from the home infusion therapy accreditation program.

(2) The home infusion therapy accrediting organization must advise the home infusion therapy supplier, in writing, of the statutory requirement for accreditation for all home infusion therapy suppliers and the possible payment consequences for a lapse in accreditation status.

(3) The home infusion therapy accrediting organization must submit their final notice of the voluntary withdrawal of accreditation by the home infusion therapy supplier to CMS by 5 business days after the request for voluntary withdrawal is ultimately processed and effective.

§488.1050 Reconsideration.

(a) General rule. A home infusion therapy accrediting organization dissatisfied with a determination that its home infusion therapy accreditation requirements do not provide or do not continue to provide reasonable assurance that the suppliers accredited by the home infusion therapy accrediting organization meet the applicable quality standards is entitled to reconsideration.

(b) Filing requirements. (1) A written request for reconsideration must be filed within 30 calendar days of the receipt of CMS notice of an adverse determination or non-renewal.

(2) The written request for reconsideration must specify the findings or issues with which the home infusion therapy accrediting organization disagrees and the reasons for the disagreement.

(3) A requestor may withdraw its written request for reconsideration at any time before the issuance of a reconsideration determination.

(c) CMS response to a request for reconsideration. In response to a request for reconsideration, CMS provides the accrediting organization with—

(1) The opportunity for a hearing to be conducted by a hearing officer appointed by the Administrator of CMS and provide the accrediting organization the opportunity to present, in writing and in person, evidence or documentation to refute the determination to deny approval, or to withdraw or not renew designation; and

(2) Written notice of the time and place of the hearing at least 10 business days before the scheduled date.

(d) Hearing requirements and rules. (1) The reconsideration hearing is a public hearing open to all of the following:

(i) Authorized representatives and staff from CMS, including, but not limited to, the

following:

(A) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(B) Legal counsel.

(C) Non-technical witnesses with personal knowledge of the facts of the case.

(ii) Representatives from the accrediting organization requesting the reconsideration including, but not limited to, the following:

(A) Authorized representatives and staff from the accrediting organization.

(B) Technical advisors (individuals with knowledge of the facts of the case or presenting interpretation of the facts).

(C) Legal counsel.

(D) Non-technical witnesses, such as patients and family members that have personal knowledge of the facts of the case.

(2) The hearing is conducted by the hearing officer who receives testimony and documents related to the proposed action.

(3) Testimony and other evidence may be accepted by the hearing officer even though such evidence may be inadmissible under the Federal Rules of Civil Procedure.

(4) The hearing officer does not have the authority to compel by subpoena the production of witnesses, papers, or other evidence.

(5) Within 45 calendar days after the close of the hearing, the hearing officer will present the findings and recommendations to the accrediting organization that requested the reconsideration.

(6) The written report of the hearing officer will include separate numbered findings of

fact and the legal conclusions of the hearing officer.

(7) The hearing officer's decision is final.

Dated: June 25, 2018.

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Seema Verma,

Administrator,

Centers for Medicare and Medicaid

Services.

Dated: June 28, 2018.

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Alex M. Azar II,

Secretary,

Department of Health and Human Services.

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