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Via Electronic Submission (www.regulations.gov)

January 4, 2016

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
ATTN: CMS-3317-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies; Proposed Rule, File Code CMS-3317-P

Dear Mr. Slavitt:

The Association of American Medical Colleges (AAMC or Association) welcomes this opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS's or the Agency's) *Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals and Home Health Agencies; Proposed Rule*, 80 Fed. Reg. 212 (November 3, 2015). The AAMC is a not-for-profit association representing all 145 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems; and, 93 academic and professional societies. Through these institutions and organizations, the AAMC represents 148,000 faculty members, 83,000 medical students, and 115,000 resident physicians.

The AAMC supports the goal of the proposed rule to provide robust patient-centered discharge planning in support of more effective care transitions to help reduce complications and readmissions. The Association believes that most of the proposed requirements are well aligned with current practices at our member institutions. Our members, particularly those who participate in alternative payment models including ACOs and bundled payments, are developing innovative approaches to discharge planning and patient education to improve patient outcomes and increase efficiency for patients and providers.

While the AAMC supports the direction of the rule, we do have some overarching concerns. When implementing modifications to the discharge planning requirements for conditions of participation (CoPs) CMS should:

- Provide maximum flexibility in delivering patient-centered care as follows:

    - Rely on risk identification and practitioner decision making to determine whether the most beneficial course of action for patients requires a full discharge plan or standard discharge instructions.
    - Allow hospitals to begin discharge planning beyond the 24 hour requirement when appropriate for certain patient populations. (E.g. multi-trauma, transplants, complex medical procedures).
- Allow for post-discharge follow-up programs to be based on individual patient needs and available social support recognizing that one size fits all approach will not benefit all patients.
- Provide clarity in how to appropriately document exceptions to the requirements.
- Ensure that any new requirements are consistent with and not counter or redundant to state requirements, particularly for the Prescription Drug Monitoring Program (PDMP) or Meaningful Use objectives such as discharge and transfer summaries.
- Recognize the true financial impact and administrative burden incurred by hospitals in implementing these requirements. We believe CMS has significantly underestimated both of these in their impact analysis.

We address additional specific provisions of the proposed rule below:

Population of Patients Required for Full Discharge Plans is too Broad

CMS is proposing that an evaluation of discharge needs and a written discharge plan be created for all inpatients and certain categories of outpatients including, but not limited to, patients undergoing surgery or same-day procedures where anesthesia or moderate sedation is used, emergency department patients who have been identified as needing a plan, and other categories of outpatients as recommended by medical staff. While the AAMC supports robust discharge planning we are concerned the proposed expansion of the patient population requiring full discharge plans will result in significant administrative burden and not necessarily benefit patients. This is counter to the goal of the new requirements.

Upon admission patients are screened for their post-discharge needs and level of risk for readmission. A stratification approach allows hospitals to identify those patients with complex medical and post-discharge needs requiring a full discharge plan. The stratification approach also identifies those patients where the most beneficial course of follow-up may be standard or extensive discharge instructions, such as in the following cases:

- Routine colonoscopy
- Skilled Nursing Facility (SNF) patient treated for a minor outpatient procedure requiring mild sedation and being discharged back to the SNF
- Young, healthy patients in for a standard outpatient procedure requiring mild sedation

As stated in the rule, there are patients who would benefit from only a set of discharge instructions and not a full discharge plan. Providing a full plan to all patients can result in confusion for patients who may have difficulty in managing the extensive planning documents. Additionally, meeting this requirement will be an excessive drain on hospital staff and will divert

scarce resources from those patients that need extensive discharge follow-up and evaluation. The AAMC recommends that all patients be evaluated for post-discharge needs in accordance with the discharge planning policies and procedures, including provider input to determine those patients that would benefit from and require a full discharge plan. The AAMC requests further clarification and guidance on whether additional documentation is necessary to account for those patients who do not warrant a full discharge plan. CMS also should consider whether some outpatient procedures, such as the examples provided above, should be excluded from the requirement for a full discharge plan.

Initiation of a Discharge Plan

The proposed rule requires that all patients must have a discharge plan initiated within 24 hours of admission or registration. This is the standard practice in most of our member institutions; however there are patients for whom it is inappropriate to begin the discharge planning within 24 hours. Academic Medical Centers primarily care for a medically complex and often vulnerable patient population. For a significant number of these patients, such as multi-trauma, transplants, burn cases, and those needing highly medical care resulting in an extended stay, discharge needs may not be immediately known at admission. A subset of these patients may also arrive unconscious with no next of kin or caregiver support making it difficult to initiate discharge planning within the proposed timeframe. Therefore, the AAMC recommends that for certain patient populations it is acceptable to document that initiating the discharge planning process will occur when the patient has progressed in his/her medical care and actual needs are more apparent. In addition, we seek clarification on how the 24 hours requirement will be implemented, what documentation will be required, and how to document for those patients where discharge planning is not feasible within the initial 24 hours.

CMS Should Provide a Longer Timeline Related to Requirements for Patients Discharged to Home

For patients being discharged to home where the follow-up care provider is known at time of discharge, CMS is proposing at §482.43(d)(3) to require the hospital to send the care provider discharge instructions and summary within 48 hours and pending test results within 24 hours of their availability. The Association believes these timing requirements will be challenging and should be modified. We recommend that urgent test results should be communicated within 24-36 hours of discharge and standard results be provided within 3-5 days. A 24 hour turn-around for non-urgent testing can put an added and unnecessary burden on providers. Similarly, a comprehensive discharge summary inclusive of all required elements is a time intensive undertaking for providers. With the increase in the number of patients requiring these summaries as well as the complex nature of the patient population at Academic Medical Centers, meeting the proposed timing criteria will place a significant burden on physicians and medical staff. The AAMC believes the timeline for providing this information should be extended.

In addition to the discharge instructions, discharge summary and pending test results, CMS proposes the hospital provide all other necessary information as specified in §482.43(e)(2) which includes the following items:

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

The AAMC appreciates the need for complete and extensive information when a patient is discharged from a hospital stay; however we are concerned that providing a discharge summary, discharge instructions, pending test results and the extensive list of required items listed above may be duplicative and in some cases excessive. For a patient is following up with his or her primary care provider many of the preventive and baseline medical history items as well as a psychosocial assessment will already be known to the provider. Additionally, functional assessments are necessary in monitoring a patient's progress and outcomes but completing an assessment for every patient is not necessary. While the extensive amount of information proposed by CMS may seem beneficial, in some cases it may be confusing for the patient and has the potential to lead to a decrease in adherence to follow-up protocols, ultimately affecting patient outcomes. At the same time the amount of information can be overwhelming for the follow-up provider and can create the risk of making it difficult to quickly identify the most critical information. The AAMC strongly recommends that CMS revise the required list for

patients discharged home to include only the information that is critical to the current plan of care, i.e., identifying active problems, goals of care, patients' and families preferences for treatment and active therapeutic interventions (including the current reconciled medication list).

Discharge Follow-Up Process

CMS is proposing a new requirement §482.43(d)(4) that hospitals establish a discharge planning process for all impacted patients. The Agency uses patient follow-up phone calls as an example of a post-discharge process. The AAMC believes that successful transitions and post-discharge care rely on efforts across the continuum of care. This may result in interventions by the hospital and/or community partners especially for the most vulnerable patient populations. Our member hospitals have been implementing a variety of discharge follow-up programs including establishment of a post-discharge hotline, follow-up appointments/phone calls and "discharge appointments" that occur with the physician while still in the hospital to address medications, test results, what to expect after discharge, etc. Many of these programs are still in their early stages and more data needs to be collected to determine which interventions have the greatest impact on patient outcomes and can be sustained financially. In determining an appropriate discharge process, hospitals should be able to stratify patients based on post-discharge needs and determine the intervention that would be most appropriate. This allows hospitals to match the follow-up with the complexity of the patient and appropriately distribute limited resources based on potential benefit.

As CMS looks toward expanding alternative payment models, consideration should be given to models that incorporate funding for post-discharge programs to improve patient follow-up and long term outcomes.

Discharge Instructions – Medication Reconciliation

In §482.43(d)(2)(iii) and §485.642(d)(2) CMS outlines the elements required for inclusion in a patient's discharge instructions including: written information on warning signs and symptoms and who to contact; prescriptions including name of drug, indication and dosage along with risks and side effects; a full reconciliation of all discharge medications with pre-hospital admission medications; and written instructions regarding follow-up care, appointments, tests and contact information.

The AAMC supports patients receiving a medication reconciliation at discharge. However there are patients for which attaining a full medication history is either difficult or not possible as they are not able to provide complete and or accurate information. For these patients, especially the most vulnerable, the hospital is not always fully aware of all medications taken prior to admission. The AAMC requests that CMS clarify the type of documentation that will substantiate that the hospital has made a reasonable effort to obtain the information but has not been successful.

It is important to note that while medication reconciliation is occurring at most of our member institutions, additional resources will be necessary to enhance the process in order to be compliant with the new requirements.

Requirements for Patients Transferred to Another Health Care Facility

The proposed rule delineates the necessary medical information that must be communicated for all patients who are being transferred to another health care facility. CMS states it plans to align the data elements with those finalized in the 2015 Edition of Health Information Technology (Health IT) Certification Criteria, Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications Final Rule which reflect "meaningful use" requirements. The AAMC strongly supports this alignment as redundancy and conflicting requirements cause an unnecessary burdens on providers and interfere with providing patients with the optimal information.

One of the data elements included in the extensive required list is psychosocial assessment. During the development of the IMPACT Act, the AAMC commented that completing a full psychosocial assessment often requires a physician or physician designee which is a significant resource intensive activity and may not be feasible for all patients being transferred. Therefore, the Association requests that CMS change the proposal so that a modified psychosocial assessment needs be completed on most patients and a full assessment only on those patients stratified by need and who a physician deems is in need of a more complete assessment.

Sharing of Post-Acute Care (PAC) Quality Data

The IMPACT Act of 2014 mandates the standardization of PAC assessment data including quality and resource use measures that can be evaluated and compared across PAC provider settings and used by hospitals to assist in care coordination. In order to implement the requirements of the IMPACT Act, CMS is proposing at §482.43(c)(8) to require hospitals to assist patients in the selection of a post-acute care provider by providing data on quality and resource use measures. While the specific domains for measures have been identified in the IMPACT Act, the measures have not yet been finalized and will be forthcoming in other rulemakings. In the interim, CMS advises hospitals to share publically reported quality data such as what is reported on Nursing Home and Home Health Compare. Hospitals must also document that they have shared this information with the patient.

The measures that CMS will finalize in future rulemakings have the potential to provide patients and their families with information that will be important to their decision making. Informed decisions about PAC providers can have a significant impact on outcomes. The AAMC requests that in addition to developing measures, the Agency develop guidance on how to effectively engage patients in a discussion of the information.

The Proposed Rule also states that discharge plans should be completed prior to discharge and a patient's discharge should not be unduly delayed due to placement in a PAC facility. AAMC

member institutions have expressed concern about how this will be monitored as patients can select a facility that has no availability or find that those with availability are not the patient's preferred facility. When this occurs, a patient's discharge may be delayed until appropriate placement is secured. Therefore, the AAMC asks CMS to clarify how time to placement will be monitored and what kind of documentation is expected.

Documenting Exceptions

As mentioned throughout this letter, there are many times when hospitals may encounter situations that do not fit within the rules. This argues for CMS to provide flexibility to hospitals, and also to ensure the availability of guidance about how to handle these situations, including documentation requirements. The following scenarios are not a complete set, but present situations of particular concern:

- Discharge plan is not initiated within 24 hours of admission because patient is a trauma patient or has an extended stay due to the need for medically complex care
- Patient is non-compliant or leaves the hospital against medical advice (AMA) and does not want to participate or sign any paperwork related to his/her discharge
- The patient is unable to provide all the information necessary to complete a full medication reconciliation
- Patient has been screened and determined to be low risk and not in need of a full discharge plan
- Patient's discharge is delayed due to difficulties related to placement in a PAC facility

Use of Prescription Drug Monitoring Program

CMS is soliciting comments on whether providers should be required to consult the Prescription Drug Monitoring Program (PDMP) in the following scenarios:

- To review patient's risk of non-medical use of controlled substances when evaluating patient's discharge needs and;
- As part of the medication reconciliation for all patients.

The AAMC believes that requiring the use of the PDMP in both of these scenarios is unnecessary. If the patient has been prescribed a controlled substance then the PDMP may be consulted; however, to require this for all patients is an inefficient use of staff resource time. Requiring the use of the PDMP for all patients will dilute the effectiveness and risks making the requirement become a "check the box procedure" rather than a valuable tool for those patients who would benefit from it the most.

Additionally, the PDMP statutes were not originally designed with discharge planning in mind and the databases have operational complexities built into their infrastructure, such as limiting access only to prescribers, which would make the implementation of this requirement onerous on the prescribing physician. As a result, the PDMP may not function appropriately for the desired use. CMS should consult state statutes to ensure alignment with authorized use and privacy restrictions.

Financial and Staffing Impact

In order to be compliant with the requirements in the proposed rule, most hospitals will need to hire additional staff, primarily to support the provision of full discharge plans to all patients and the required information to be completed prior to discharge including medication reconciliation. This increase in staffing will have a significant financial and resource impact on hospitals and does not include any additional resources or staffing required to meet the other proposed requirements. For example, as one member reports that it is currently performing complex assessments on approximately 55% of inpatients who are identified during the risk screening process. To comply with the requirement to complete a full assessment on all patients would result in the care management staffing budget to nearly double from approximately 7.3 million dollars to over 14 million dollars. Similarly, while members have implemented a variety of discharge follow-up programs, many of them are costly to operate. Several members have indicated their discharge follow-up call programs cost approximately one million dollars per year to operate and many of these programs are currently being operated under grant funding.

As the AAMC has stated previously, the need for comprehensive discharge information is critical for both patients and providers; however the requirement that full discharge plans be required for all inpatients and certain outpatients does not appear to benefit all patients while at the same time re-directing limited resources that could be better used elsewhere. We believe CMS has significantly underestimated the financial impact on hospitals in their impact analysis and should consult with hospitals to determine the true cost of implementing these changes.

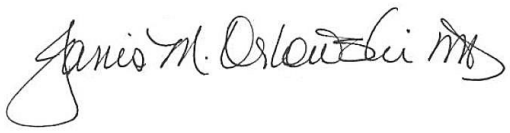
Clarification and Transparency in Implementation and Monitoring

The AAMC appreciates that much of the clarification of these requirements will be included in the interpretative guidance. It is important that CMS develop this guidance through an inclusive and transparent process that offers opportunities for stakeholder feedback. To ensure that hospitals have the information they need to comply with the requirements it is critical that CMS be clear about how to implement all requirements and that the Agency be transparent about the monitoring metrics it will use.

CONCLUSION

Thank you for the opportunity to present our views. The AAMC would welcome the opportunity to work with CMS on any of the issues discussed above including sharing best practices from our member institutions or other topics that involve the academic health center community. If you have questions regarding our comments, please feel free to contact Jennifer Faerberg, jfaerberg@aamc.org or 202-862-6221.

Sincerely,



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