

Summary of Public comments on the Medicare Outpatient Observation
Notice (MOON)

CMS-10611

Comment: We received numerous comments regarding the general formatting and readability of the MOON. Several commenters expressed concern that the MOON was too complex for patients to have a full understanding of the issues included in the notice and the implications of being an outpatient receiving observation services. Some commenters did not consider the MOON to be written in 'plain language'. Some commenters suggested the reading level of the MOON was too advanced for the typical beneficiary. Another commenter noted that the MOON is written at a 12.1 grade level and cited a study that claims that the average American's reading level proficiency is generally to be considered to be 5th to 7th grade level. Some commenters made suggestions on how the MOON could be reordered and simplified to improve understandability and effectiveness. Commenters also thought there were duplicative time and date fields as well as unnecessary fields for physician and hospital names when that information can be found in the beneficiary's medical record, or can be otherwise printed on the top of the notice, in the case of the hospital name. One commenter wanted the MOON to have more room for the beneficiary's name and date of birth while another commenter wanted the MOON limited to one page. Another commenter provided copies of state issued

observation notices as examples we may wish to consider during this notice development process. Other commenters suggested specific language for revising the notice. One commenter proposed incorporating a question and answer format on the MOON. Some commenters were concerned with which physician (admitting or attending) name should be included on the MOON. Other commenters did not want a requirement to include a physician name on the notice as many physicians at a hospital can be involved with a beneficiary's outpatient care.

Response: We agree with the commenters that some fields are unnecessary when the information is contained in the patient's medical record. To that end, we have reduced the number of fillable fields on the MOON. Specifically, the fields for physician name and the date and time observation services began are no longer on the notice. In addition, we removed the field for the hospital name. Consistent with requirements for current beneficiary notices, and detailed in future guidance, hospitals will be permitted to preprint the MOON to include their hospital name and logo at the top of the notice.

We are unable to condense the MOON into a single page as condensing the notice would negatively affect its readability. We do note that hospitals may print the MOON as two sides of a single page. Finally most of the language in the MOON is required by statute and therefore, cannot be removed. CMS Office of Communications has performed a plain language review and we have incorporated those changes, wherever possible. The notice is now

more streamlined and easier to comprehend. The MOON was developed using, where possible, language from previously approved beneficiary publications and the notice was subject to plain language review by the Office of Communications. CMS doesn't routinely use specific readability tests on beneficiary publications. We appreciate the commenters' concerns and have made changes to the MOON, as discussed above, in order to help ensure maximum readability and comprehension. In addition to these revisions, the MOON will be updated periodically, so there will be future opportunities to revise the notice based on stakeholder experience with the MOON.

Comment: We received numerous comments related to the notice section containing contact information to express quality of care concerns to QIOs. Some commenters suggested moving this section further down or to the end of the notice. Other commenters suggested removing this information entirely. Some commenters explained that inclusion of this contact information would be confusing to beneficiaries and could mislead them as to the purpose of this notice. One commenter recommended revising the language to specifically state that QIOs do not have the authority to change a patient's status from observation to inpatient. Some commenters suggested that the inclusion of QIO contact information may encourage calls to the QIO expressing that the beneficiary should be an inpatient, rather than outpatient, and regard the outpatient status as a quality of care, rather than

level of service. Another commenter suggested we amend the QIO scope of work to account for additional inquiries that may result when required MOON delivery begins. Yet another commenter believed the information about filing complaints with Medicare Advantage plans is unnecessary. That commenter expressed concern that because outpatient status is not appealable, this contact information may cause unnecessary confusion.

Response: We have carefully considered all of these comments and found the commenters suggesting removal of this section to be particularly persuasive. Therefore, we have removed this section from the MOON. We agree that doing so will keep the focus of the MOON on related coverage and cost sharing implications.

Comment: One commenter suggested that CMS remove the requirement directing a patient to contact 1-800-MEDICARE with questions, and replace that entire paragraph with hospital contact information. The commenter reasoned that because hospitals provide robust financial counseling services, physician advisors, care management teams, etc., they can better answer beneficiary questions in a friendly, in person manner. Conversely, another commenter recommended removing the language referring beneficiaries with questions to hospital staff and physicians. This commenter believed that beneficiary questions regarding coverage and financial

responsibility for observation services are more appropriately directed to 1-800-MEDICARE. Another commenter suggested that CMS establish a point of contact in addition to 1-800-MEDICARE for questions related to the MOON.

Response: The MOON's inclusion of 1-800-Medicare contact information is consistent with other beneficiary notices. In addition to observation stay questions, beneficiaries may have other concerns related to billing, coverage, and associated issues.

We are maintaining the MOON's direction of patients to hospital personnel, in general, rather than to specific hospital contacts, to afford hospitals flexibility in the contact information they provide. However, hospitals may use the additional information section to specify particular hospital staff members and their contact information.

Finally, we believe that beneficiary needs are satisfied by the existing options of 1-800-Medicare as well as by hospital staff. Beneficiaries have access to broad benefit and coverage information through 1-800-Medicare, and case specific information from their hospital. Therefore, an additional point of contact is not necessary.

Comment: Several commenters explained that the MOON does not clearly state that the patient is not an inpatient for the purposes of meeting the 3-day qualifying stay for coverage of skilled nursing facility

services, following a hospital stay. One commenter thought that the MOON should explain the potential financial implications of being classified as an outpatient, rather than an inpatient, in simple, easy to understand terms. Another commenter noted that the MOON includes complex phrases such as “observation stay” and “prior qualifying inpatient hospital stay” without explanation. The commenter stated if these specific terms must be used, they should be defined in the notice. Many commenters suggested clarifying Part B coverage info and moving that language up in the ordering of the notice. One commenter suggested specific language to more clearly convey the information contained in this section.

Response: We agree with the commenters that this important information regarding coverage in skilled nursing facility, subsequent to an observation stay, should be more clearly stated and prominently displayed on the notice. To that end, we have simplified this language as part of the MOON’s plain language review, and moved it near the top of the MOON.

Comment: Several commenters indicated that the NOTICE Act requires hospitals to explain the reason patients are classified as outpatients rather than inpatients. These commenters recommended that the MOON include a section for physicians to indicate the reason for outpatient status. Another commenter suggested that the MOON contain standard language explaining

that the decision to classify a beneficiary as an outpatient, rather than admit as an inpatient, is based on Medicare regulations, without regard to cost-sharing responsibilities or skilled nursing facility eligibility. One commenter requested that CMS provide standard narratives to be used by hospitals when explaining the possible reasons for outpatient classification.

Conversely, another commenter was satisfied with the MOON's standard language regarding the "reason" for observation services. However this commenter thought this language was not clearly and prominently communicated on the notice.

Response: We agree with the commenters who thought that the MOON should contain a field where a hospital will be required to state the specific reason a beneficiary is an outpatient, rather than inpatient. We believe this recommendation is consistent with the statute. The MOON now contains a free text field where the specific reason for being in an observation stay will be stated. We will consider, in future iterations of the MOON, checkboxes with common reasons for the patient's outpatient status or suggested narratives for insertion in this section. Given this notice's statutory mandate and tight implementation timeframes it is not feasible for us to thoughtfully develop such language at this time. When preparing for MOON implementation, or in the future, hospitals may wish to develop their own predetermined observation status reasons for inclusion in this section. We are affording hospitals the ability to do so in the interest of simplifying delivery of the MOON wherever possible. In the future, we wish to receive

input from industry and beneficiary advocates regarding this type of notice content improvement.

Comment: Several commenters asked that CMS clarify what additional information is expected to be included in the Additional Information space on the MOON.

Response: We generally do not specify expected language for the additional information sections of beneficiary notices. However, we can make suggestions to items hospitals may find useful to include in this space on the MOON. Hospitals may wish to include unique circumstances regarding the particular patient such as Accountable Care Organization (ACO) information, notation that a beneficiary refused to sign the MOON, hospital waivers of the beneficiary's responsibility for the cost of self-administered drugs, and specific information for contacting hospital staff.

Comment: One commenter asked whether hospitals that provide their own notice to all patients receiving observation services would still need to provide the MOON to Medicare beneficiaries who have received 24 hours of observation services as an outpatient.

Response: We recognize that some hospitals may voluntarily issue a notice to outpatients, or in some cases to outpatients who have received observation services, informing patients of the implications of being an

outpatient on cost sharing and benefits. However, the NOTICE Act requires hospitals and CAHs to furnish written notice specified by the Secretary pursuant to rulemaking, containing such language as the Secretary prescribes. Given the statutory language and intent of the NOTICE Act, we believe the federal standardized notice (the MOON) must be delivered to Medicare beneficiaries entitled to notice under the NOTICE Act, consistent with the provisions of this final rule, notwithstanding any similar notice that hospitals may also have to deliver to patients pursuant to state law or otherwise.

Comment: Several commenters requested specification on whether it was necessary for hospitals to retain a signed copy of the completed MOON in the patient's medical record and how the requirements for doing so. One commenter asked whether hospitals could document in the medical record that the MOON was provided to the patient and an oral explanation was furnished without retaining a copy of the notice. Another commenter asked that CMS clarify hospitals can obtain an electronic signature and retain the MOON only in electronic form. One commenter asked CMS to clarify if there is a mechanism for hospitals to provide, when necessary, evidence the notice was delivered to the patient.

Response: Consistent with our longstanding policy, we will require that hospitals retain a signed copy of the MOON. Such a practice ensures both

hospitals and surveyors that the appropriate notices have been delivered as required. However, in the past we have permitted providers to determine the method of storage. This same flexibility will be afforded to hospitals delivering the MOON. Hospitals may choose to retain a signed notice as a hardcopy, or electronically.

Comment: We received several comments suggesting that the signature of a beneficiary reflect notice comprehension, as well as receipt of the notice.

Response: We clarify that a notice signature will reflect notice receipt as well as comprehension, consistent with statutory requirements that the notice be written and formatted using plain language and be accompanied by a verbal explanation. We note this requirement that a beneficiary must be known to understand a notice, and that the signature reflects this understanding, is consistent with other beneficiary notices. The MOON, as well future instructions, makes clear that the signature attests to both receipt and understanding of the notice. We will be publishing guidance, pursuant to our usual approval process, to further guide providers in delivery of the MOON. We plan for this guidance to be available to providers before notice delivery is required.