

## **MOON: 30-day Comment Responses**

### **December 1, 2016**

1. Staff signature when a beneficiary refuses to sign:

Commenters expressed concern regarding a beneficiary's refusal or inability to sign, and indicated the need for guidance in these circumstances. Some commenters suggested a staff signature line, which we have addressed in response 3 below.

The NOTICE Act expressly requires that if such individual entitled to notice or person acting on such individual's behalf refuses to provide signature, the MOON be signed by the staff member of the hospital or CAH who presented the written notification and include the name and title of such staff member, a certification that the notification was presented, and the date and time the notification was presented (in accordance with section 1866(a)(1)(Y)(ii)(IV)(bb) of the Act).

2. Patients unable to sign:

The NOTICE Act requires hospitals and CAHs to deliver written notice to an individual who has received more than 24 hours of observation services as an outpatient, and requires hospitals and CAHs to document acknowledgment of receipt of the notice by obtaining a signature of the individual or the person acting on the individual's behalf. The NOTICE Act also provides a mechanism for hospitals and CAHs to comply with the acknowledgment requirement if the individual or person acting on behalf of the individual refuses to sign the written notice. We plan to issue instructions in the CMS Internet Only Manual and Chapter 13 of the Medicare Managed Care Manual.

3. "Additional Information" section to include notation for a beneficiary's refusal to sign:

We generally do not specify expected language for the additional information sections of beneficiary notices. However, we believe hospitals and CAHs may use this section to include information such as unique circumstances regarding the particular patient (such as Medicare Accountable Care Organization (ACO) information), a notation that a beneficiary refused to sign the MOON (along with the staff member's signature and pertinent information as noted in 1 above), hospital waivers of the beneficiary's responsibility for the cost of self-administered drugs, Part A cost sharing responsibilities if the beneficiary is subsequently admitted as an inpatient, or specific information for contacting hospital staff.

4. Ethical concerns regarding staff signature:

We appreciate the concerns raised by the commenter. However, the NOTICE Act expressly requires that if such individual entitled to notice or person acting on such individual's behalf refuses to provide signature, the MOON be signed by the staff member of the hospital or CAH who presented the written notification and includes the name and title of such staff member, a certification that the notification was presented,

and the date and time the notification was presented (in accordance with section 1866(a)(1)(Y)(ii)(IV)(bb) of the Act). We believe accepting something in lieu of signature of the individual, person acting on individual's behalf, or relevant staff member would be inconsistent with the rules at § 489.20(y).

5. Appeal Rights/ SNF Requirement:

We believe these concerns are outside the scope of the NOTICE Act and reflect a misunderstanding of the nature of the notice required under the statute and final regulations. We disagree with the commenter's assertion that delivery of the MOON constitutes a determination of noncoverage of a post-hospital SNF care. We also disagree with the commenter's characterization of the proposed MOON constituting a notice of denial of coverage in general. Finally, we do not believe the MOON is the appropriate document to communicate appeal rights; the Medicare Summary Notice (MSN) fulfills that purpose. Therefore, we are not accepting the commenters' recommendations.

As we noted in the final rule, the MOON is a required informational/educational notice regarding patient status provided by a hospital or CAH when the beneficiary is still in the hospital or CAH and receives observation services as an outpatient for more than 24 hours. The MOON explains the current status of the patient as an outpatient and not an inpatient, in addition to the implications of being an outpatient receiving observation services. As we explained in the final rule delivery of the MOON does not constitute an initial determination issued in response to a claim for benefits, and the MOON itself is not a notice of an initial determination (81 FR 25134). Furthermore, delivery of the MOON by a hospital or CAH does not constitute a denial of coverage of any services, and does not constitute a noncoverage decision with respect to post-hospital SNF care as asserted by the commenter. In fact, generally beneficiaries will still be receiving care when the MOON is delivered and will sometimes be formally admitted as inpatients after delivery of the MOON.

The NOTICE Act does not provide for appeal rights regarding the notice itself. The NOTICE Act also does not afford any new appeal rights beyond those already available (under section 1869 of the Social Security Act), nor does the NOTICE Act limit or restrict currently available appeal rights. Consistent with the legislation, the final rule did not expand or limit appeal rights. For the reasons discussed above, we are not adopting the various recommendations with respect to amending the MOON to include appeal rights or an explanation of the lack of appeal rights.

As we noted in the final rule, the decision to admit a beneficiary as an inpatient is a complex medical decision made by the physician in consideration of various factors, including the beneficiary's age, disease processes, comorbidities, and the potential impact of sending the beneficiary home. It is the responsibility of the physician to make the complex medical determination of whether the beneficiary's risk of morbidity or mortality dictates the need to remain at the hospital because the risk of an adverse event would otherwise be unacceptable under reasonable standards of care, or whether the

beneficiary may be discharged. We expect that the NOTICE Act and implementing policies will result in beneficiaries having a better understanding of the care they receive.

6. Recipients of the MOON:

The NOTICE Act explicitly states that hospitals and CAHs are required to furnish notice to an individual who receives observation services as an outpatient at such hospital or CAH for more than 24 hours, and we proposed to implement this provision (delivery of the MOON) requiring hospitals and CAHs to provide the required notice to just that population of notification recipients. We do not believe it would be appropriate to expand the population of notification recipients, as the statute expressly provides the scope of that population. Therefore, we do not require hospitals and CAHs to furnish the MOON to outpatients other than those who have received observation services as outpatients for more than 24 hours, as set forth in the statute. However, per § 489.20(y), hospitals and CAHs may deliver the MOON to individuals receiving observation services as an outpatient before such individuals have received more than 24 hours of observation services, and be in compliance with the written delivery requirements set forth in the NOTICE Act.

Further, we emphasize that MOON statutory requirements do not supersede mandatory delivery of existing beneficiary notices such as the Important Message from Medicare. Our beneficiary notices meet requirements for specific situations and must be kept separate to ensure that each notice is readable, easy to comprehend, and focused on each individual notice purpose.

Finally, for any delivery situation necessitating guidance, such as beneficiaries who begin as outpatients but are later admitted, instructions will be included in the CMS Internet Only Manual and Chapter 13 of the Medicare Managed Care Manual.

7. MA Requirement:

We agree with the commenter that some of the FFS rules, such as use of Condition Code 44, are not required in the MA program. As we stated in the final rule, we recognize that MA plans may have certain rules that differ from original Medicare and that these variances may result in some of the information in the MOON being inapplicable to some MA enrollees. For example, under an MA plan's benefit structure, the enrollee may not need to have a 3-day qualifying inpatient hospital stay in order to qualify for coverage of post-hospital SNF care. However, we do not believe it would be appropriate to exclude MA enrollees from the requirement that a hospital or CAH deliver the MOON to any beneficiary who receives observation services as an outpatient for more than 24 hours. In developing the MOON, we have attempted to mitigate the potential variation between original Medicare and MA by directing MA enrollees who receive the MOON to contact their plans for specific information that may be relevant to the receipt of outpatient observation services. As we explained in the final rule, the MOON must be delivered while the individual is in the hospital receiving

outpatient observation services. Specifically, pursuant to section 1866(a)(1)(Y) of the Act and the regulatory provision at § 489.20(y), hospitals and CAHs must provide notice to an individual who receives observation services as an outpatient for more than 24 hours, and such notice must be furnished no later than 36 hours after observation services are initiated, or sooner if the individual is transferred, discharged, or admitted as an inpatient. If, as described in the commenter's example, the individual is initially admitted to a hospital or CAH as an inpatient, the requirement to deliver the MOON does not apply (in cases where the individual receives outpatient observation services for fewer than 24 hours prior to the inpatient admission), notwithstanding any later determination by the MA plan (following the individual's discharge) related to the inpatient hospital admission. It is our expectation that a contracted hospital and the MA plan coordinate and communicate regarding the appropriate level of care while the enrollee is receiving care in the contracted hospital in accordance with the requirements at § 422.112 related to continuity of care and integration of services.

As noted in the final rule, a beneficiary enrolled in an MA or other Medicare health plan would receive the required notice under the existing rules that apply to hospitals and CAHs under a provider agreement governed by the provisions of section 1866(a)(1)(Y) of the Act. The MA regulations related to selection and credentialing of contract providers at § 422.204(b)(3) require that, with respect to providers that meet the definition of "provider of services" as defined in section 1861(u) of the Act, basic benefits may only be provided by these providers if they have a provider agreement with CMS permitting them to provide services under original Medicare. Given the statutory language in section 1866 of the Act and the regulatory requirements in 42 CFR Part 422 related to provider agreements, we do not believe it would be appropriate to exclude hospitals and CAHs from the NOTICE Act requirements with respect to MA enrollees. Therefore, as stated in the final rule, hospitals and CAHs must furnish the MOON to MA enrollees who receive observation services as an outpatient for more than 24 hours.

8. Medicare, Duals or MA as secondary insurance:

The provisions of the NOTICE Act amended section 1866 of the Act and apply to hospitals and CAHs furnishing services to individuals entitled to benefits under Title XVIII of the Act, whether or not the services are payable under Title XVIII. If an individual is entitled to benefits under Title XVIII (and receives observation services as an outpatient for more than 24 hours), the notice requirement applies, regardless of whether Medicare is the secondary payer. The applicability of the notice requirement depends on whether the individual is entitled to benefits under Title XVIII, not on whether Medicare makes payment (primary or otherwise).

9. Timing of Delivery:

Under the statute, the notice and explanation must be delivered no later than 36 hours after the time such individual begins receiving observation services (or, if sooner, upon release). We specified in proposed § 489.20(y) that the notification required by section 1866(a)(1)(Y) of the Act must be provided to individuals entitled to benefits under Title

XVIII of the Act, whether or not the services furnished are payable under Title XVIII, when individuals receive observation services as an outpatient for more than 24 hours. As we stated in the final rule, for outpatients who are receiving observation services but not for more than 24 hours, hospitals and CAHs would not be required to deliver notice (81 FR 25132).

We agree that the statute provides latitude to permit a hospital or CAH to voluntarily deliver notice prior to an individual's receipt of more than 24 hours of observation services as an outpatient. The NOTICE Act requires notice to individuals receiving more than 24 hours of observation services as an outpatient. While hospitals are not required to deliver notice to an individual who has not received more than 24 hours of observation services as an outpatient, nothing in the statute precludes hospitals and CAHs from delivering notice before an individual has received more than 24 hours of observation services as an outpatient, provided the information contained in the notice is accurate. For example, hospitals and CAHs that are subject to State laws requiring written notice to outpatients receiving observation services within 24 hours of the initiation of services, may deliver the MOON to those individuals it believes will trigger the required notice under the NOTICE Act during the State-mandated timeframes and still be in compliance with the timing of notice delivery requirement of the NOTICE Act (provided the MOON is delivered not later than 36 hours after the time such individual begins receiving outpatient observation services, or, if sooner, upon release (that is, sooner, if transferred, discharged, or admitted as an inpatient)). Per the regulation at § 489.20(y), hospitals and CAHs may deliver the MOON before an individual has received more than 24 hours of observation services as an outpatient.

However, we reiterate that the notice required by the NOTICE Act must be delivered within the timeframe established in statute; that is, no later than 36 hours after the time an individual begins receiving observation services as an outpatient, or if sooner, if the individual is transferred, discharged, or admitted. Delivering notice after this timeframe (for example, within 48 hours of the initiation of observation services, as suggested by one commenter) would not comply with the NOTICE Act requirement for timing of notice delivery.

#### 10. Code 44 notice:

As we have previously stated in Chapter 1, Section 50.3 of the Medicare Claims Processing Manual, CMS set the policy for the use of Condition Code 44 to address those relatively infrequent occasions, such as a late-night weekend admission when no case manager is on duty to offer guidance, when internal review subsequently determines that an inpatient admission does not meet hospital criteria and that the patient would have been registered as an outpatient under ordinary circumstances. Use of Condition Code 44 is not intended to serve as a substitute for adequate staffing of utilization management personnel or for continued education of physicians and hospital staff about each hospital's existing policies and admission protocols. As education and staffing efforts continue to progress, the need for hospitals to correct inappropriate admissions and to report Condition Code 44 should become increasingly rare.

#### 11. Content, Formatting and Readability:

In response to the suggestion to condense the MOON into a single page, we are unable to do so, as condensing the notice would negatively affect its readability; for example, reducing the notice to one page would require use of an extremely small font size. However, we note that hospitals may print the MOON as two sides of a single page. Finally, we have drafted the MOON to contain all of the elements of notice we believe are required under the NOTICE Act. The CMS Office of Communications has performed a plain language review, and suggested changes were incorporated into the notice. We do not routinely use specific readability tests on beneficiary notices. Prior to publication of the 30-day notice and comment period, we made several changes to the MOON that we believe enhance readability and comprehension. Further, the MOON is now formatted similarly to related beneficiary notices that have undergone consumer testing and have been successfully in use for many years. We believe, as a result of these extensive changes, the notice is now more streamlined and easier to comprehend. In addition to these revisions, as with most beneficiary notices, we expect that the MOON will be updated periodically based on our continued experience with the notice, through the PRA renewal process which requires reapproval every 3 years. Therefore, we will accept and consider feedback during these renewal periods to inform and improve future iterations of the MOON.

#### 12. Post-hospital SNF care and Part B coverage:

To address concerns related to coverage of post-hospital SNF care and Part B coverage, the language in the draft notice posted during the 30-day comment period had been simplified and moved to near the top of the MOON.

#### 13. State v. Federal notification:

The MOON must be delivered to Medicare beneficiaries pursuant to § 489.20(y), notwithstanding any similar notice that hospitals may have to deliver to such patients under State law or otherwise. In some cases, delivering the MOON may also fulfill State notice requirements for the Medicare population. Hospitals and CAHs will need to make that determination on a State-by-State basis. As explained in the final rule, where State law requires content that is not included in the MOON, hospitals may utilize the free text field in the MOON (“Additional Information”) for communicating such additional content. Hospitals and CAHs subject to State law notice requirements may also attach an additional page to the MOON to supplement the free text field in order to communicate additional content required under State law, or may attach the notice required under State law to the MOON. To the extent that there are requirements in a State law that directly conflict with or contradict requirements in the NOTICE Act, we will expect to address those issues of preemption as they are brought to our attention. However, at this time, we are not aware of any such State laws that contradict or conflict with the provisions of the NOTICE Act.

14. Retention policies:

Consistent with longstanding practice in implementing beneficiary notices, we will require that hospitals and CAHs retain a signed copy of the MOON. Such a practice assures both hospitals and CAHs 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 and CAHs delivering the MOON. Hospitals and CAHs may choose to retain a signed notice as a hard copy or electronically.

15. Part B cost sharing information:

While Part B cost-sharing amounts for physician services do not differ based on the inpatient or outpatient status of the beneficiary, we still believe the statute requires the MOON to include information on Part B cost-sharing for physician services as it is part of the total cost-sharing for which the beneficiary is responsible.

16. Language availability:

A number of commenters requested that CMS provide the MOON in alternate languages. Some specifically requested that CMS provide the MOON in the top 15 languages nationally. We appreciate commenters' concerns that beneficiaries have access to the MOON in a language they understand. As stated in the final rule, we will provide the MOON in both English and Spanish. We believe hospitals and CAHs already have in place various procedures to ensure that beneficiaries are able to understand notices and information delivered to them, and we expect they can further utilize those procedures to deliver the MOON. In addition, we believe that the requirements under section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964, as listed in the final rule, mandate that hospitals and CAHs have the responsibility to provide language assistance to LEP individuals, and that these requirements apply to delivery of the MOON. Therefore, we are not accepting the commenters' recommendations.

17. Implementation:

As noted in the final rule, the MOON is following the established OMB notice approval process under PRA. Once the MOON is approved through the PRA process, hospitals and CAHs must fully implement use of the MOON and comply with all of the NOTICE Act requirements no later than 90 calendar days from the date of OMB approval. This will be announced on the CMS Beneficiary Notices Initiative Web site at: <https://www.cms.gov/Mdicare/Medicare-General-Information/BNI/index.html> and in an HPMS memorandum to MA plans. We believe this affords hospitals and CAHs with adequate time to prepare for implementation, consistent with past implementation practices for beneficiary notices.

18. Enforcement/Repercussions:

We appreciate commenters' interest in the oversight of MOON delivery. All monitoring and enforcement of the MOON will be consistent with our oversight procedures for other hospital delivered notices. We are reviewing our surveying protocols to identify changes that may be needed to facilitate effective monitoring and enforcement of these requirements. These revised procedures will be developed and implemented in the normal course of business.

19. Issuance/Staffing requirement:

We generally do not prescribe which hospital staff member must deliver a notice to a beneficiary. We agree with the commenter that the hospital or CAH is in the best position to determine the appropriate staff member to deliver the MOON. We clarify that inclusion of a particular occupation in a burden estimate reflects our attempts to best approximate, while not underestimating, the anticipated costs of notice delivery. This occupation choice does not serve as a notice delivery staff requirement.

20. Oral Explanation:

The statute requires that there be an oral explanation of the written notification, or MOON. We believe it is essential that hospital staff are available to provide a verbal explanation and answer questions in the interest of beneficiaries fully understanding the MOON. A video presentation of the MOON is acceptable if an individual is available to answer questions. Finally, the NOTICE Act requires hospitals and CAHs to deliver both a written notice and an oral explanation of the notice when notice delivery is required. Therefore, we do not believe providing only an oral notice is permissible under the statute.

21. Underestimated burden:

Some commenters noted that the burden estimate does not adequately account for the time to gather and enter the necessary data and information (including the information to be inserted into the free-text fields), review the instructions, complete and review necessary responses, and deliver the notice to the beneficiary. The burden estimates were not intended to include time spent on customary and usual business practices, which may account for commenters' concerns with the estimate. We did not break out the impact on CAHs and non-CAHs separately, as we anticipate a general, comparable burden on CAHs and hospitals.

As a result of comments received on the 30-day PRA notice, we have reassessed our proposed burden estimate and have increased the estimated time for hospitals to prepare and deliver the MOON from 15 minutes to 30 minutes. This slight increase addresses the public comments received on the 30-day PRA notice for the MOON. We believe the

increase from 15 minutes to x minutes adequately accounts for additional time spent complying with the MOON delivery requirements.

22. Burden placed on hospitals:

As we noted in the final rule, we believe that hospitals and CAHs furnishing observation services are sufficiently staffed to furnish such observation services and that hospitals and CAHs would appropriately train the staff that furnishes observation services to deliver the MOON, as required, in the applicable cases.

23. Out of Scope Comments:

We received several comments that were outside the scope of the provisions of the final rule and do not specifically relate to the content of the MOON or the instructions that are the subject of the 30 day PRA notice. As such, we are not responding to them. These comments were related to (1) beneficiary education and outreach; (2) provider education and outreach; and (3) pressure placed on providers to admit beneficiaries as inpatients.

24. LEP Requirements:

We appreciate commenters' concerns that beneficiaries have access to the MOON in a language they understand. As stated in the final rule, we will provide the MOON in both English and Spanish. We believe hospitals and CAHs already have in place various procedures to ensure that beneficiaries are able to understand notices and information delivered to them, and we expect they can further utilize those procedures to deliver the MOON. In addition, we believe that the requirements under section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964, as listed above, mandate that hospitals and CAHs have the responsibility to provide language assistance to LEP individuals, and that these requirements apply to delivery of the MOON. Therefore, we are not accepting the commenters' recommendations.

1. Removal of QIO information:

We agree with the commenters' suggestion to keep the focus of the MOON on status as an outpatient and related coverage and cost-sharing implications. Therefore, we have removed the QIO contact section from the MOON.

26. Addition of Free Text field with specific reason for being outpatient versus inpatient:

The inclusion of this field is consistent with the statute, specifically section 1866(a)(1)(Y)(ii)(I) of the Notice Act. The MOON now contains a free text field where the specific reason for receiving observation services as an outpatient shall be completed by the hospital or CAH. Further, we may consider, in the future, the other suggestions

commenters made to improve the MOON, such as checkboxes with common reasons for the patient's outpatient status or suggested narratives for insertion in this section. We expect that the MOON will be updated periodically based on our continued experience with the notice, through the PRA renewal process, which requires reapproval every 3 years.