CMS Manual System	Department of Health & Human Services (DHHS)					
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)					
Transmittal 3695	Date: January 20, 2017					
	Change Request 9935					

SUBJECT: Medicare Outpatient Observation Notice (MOON) Instructions

I. SUMMARY OF CHANGES: The purpose of this change request (CR) is to update Chapter 30 of Pub. 100-04 to include the Medicare Outpatient Observation Notice (MOON), CMS-10611, form instructions. The MOON was developed to inform all Medicare beneficiaries when they are an outpatient receiving observation services, and are not an inpatient of the hospital or critical access hospitals (CAH). The form instructions to be included in Chapter 30 provide guidance for proper issuance of the MOON.

EFFECTIVE DATE: February 21, 2017

*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: February 21, 2017

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE				
R	30/Table of Contents				
N	30/400/ Part A Medicare Outpatient Observation Notice				

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements Manual Instruction

Attachment - Business Requirements

Pub. 100-04 Transmittal: 3695 Date: January 20, 2017 Change Request: 9935

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I. GENERAL INFORMATION

A. Background: This CR updates Chapter 30 of Pub. 100-04 to include the MOON, CMS-10611, form instructions. The MOON was developed to inform all Medicare beneficiaries when they are an outpatient receiving observation services, and are not an inpatient of the hospital or CAH. The MOON is mandated by the Federal Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act), passed on August 6, 2015.

B. Policy: The NOTICE Act (Pub. L. 114-42).

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME Shared-System Maintainers				tainers	Other
		A	В	ННН	MAC	FISS	MCS	VMS	CWF	
9935.1	Hospitals shall observe the inclusion in Chapter 30 of the MOON and its instructions in Chapter 30 of Pub. 100-04.	X	X							Hospital, Providers
9935.1.1	Contractors shall be aware that this CR and its content are informational only for contractors. There are no actions contractors must take to distribute or process the MOON when it is submitted as part of the patient medical record.	X	X							Providers

III. PROVIDER EDUCATION TABLE

Number	Requirement	Re	spor	nsibility	,	
			A/ M/		DME MAC	CEDI
		A	В	ННН		
9935.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web sites and include information about it in a listserv message within 5 business days after receipt of the notification from CMS announcing the availability of the article. In addition, the provider education article shall be included in the contractor's next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X	X			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements:

[&]quot;Should" denotes a recommendation.

X-Ref	Recommendations or other supporting information:
Requirement	
Number	

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Janet Miller, 404-562-1799 or Janet.Miller@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

ATTACHMENTS: 0

Medicare Claims Processing Manual Chapter 30 - Financial Liability Protections

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400 - Part A Medicare Outpatient Observation Notice

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400.2- Scope

400.3- Medicare Outpatient Observation Notice

400.4- Intersection with State Observation Notices

400 - Part A Medicare Outpatient Observation Notice (Rev. 3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

The MOON informs all Medicare beneficiaries when they are an outpatient receiving observation services, and are not an inpatient of the hospital or critical access hospital (CAH).

400.1- Statutory Authority (Rev. 3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

On August 6, 2015, Congress enacted the Notice of Observation Treatment and Implication for Care Eligibility Act (NOTICE Act) Public Law 114-42, amending Section 1866(a)(1) of the Social Security Act (the Act) (42 U.S.C. 1395cc(a)(1)), by adding a new subparagraph (Y). The NOTICE Act requires hospitals and CAHs to provide written and oral explanation of such written notification to individuals who receive observation services as outpatients for more than 24 hours.

The process for delivery of this notice, the Medicare Outpatient Observation Notice (MOON), was addressed in rulemaking, including a final rule, CMS-1655-F (81 FR 56761, 57037 through 57052, August 22, 2016), effective October 1, 2016. The resulting regulations are located at 42 CFR Part 489.20(y).

400.2- Scope (Rev.3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

The MOON must be delivered to beneficiaries in Original Medicare (fee-for-service) and Medicare Advantage enrollees who receive observation services as outpatients for more than 24 hours. The hospital or CAH must provide the MOON no later than 36 hours after observation services as an outpatient begin. This also includes beneficiaries in the following circumstances:

- Beneficiaries who do not have Part B coverage (as noted on the MOON, observation stays are covered under Medicare Part B).
- Beneficiaries who are subsequently admitted as an inpatient prior to the required delivery of the MOON.
- Beneficiaries for whom Medicare is either the primary or secondary payer.

NOTES:

- For purposes of these instructions, the term "beneficiary" means either beneficiary or representative, when a representative is acting for a beneficiary.
- Please see Chapter 13 of the Medicare Managed Care Manual for Medicare Advantage instructions.

The statute expressly provides that the MOON be delivered to beneficiaries who receive observation services as an outpatient for more than 24 hours. In other words, the statute does not require hospitals to deliver the MOON to all beneficiaries receiving outpatient services. The MOON is intended to inform beneficiaries who receive observation services for more than 24 hours that they are outpatients receiving observation services and not inpatients, and the reasons for such status, and must be delivered no later than 36 hours after observation services begin. However, hospitals and CAHs may deliver the MOON to an individual receiving observation services as an outpatient before such individual has received more than 24 hours of observation services. Allowing delivery of the MOON before an individual has received 24 hours of observation services affords hospitals and CAHs the flexibility to deliver the MOON consistent with any applicable State law that requires notice to outpatients receiving observation services within 24 hours after observation services begin. The flexibility to deliver the MOON any time up to, but no later than, 36 hours after observation services begin also allows hospitals and CAHs to spread out the delivery of the notice and

other hospital paperwork in an effort to avoid overwhelming and confusing beneficiaries.

Hospitals Affected by these Instructions. These instructions apply to hospitals as well as CAHs per section 1861(e) and section 1861(mm) of the Social Security Act.

400.3- Medicare Outpatient Observation Notice (Rev. 3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

The MOON is subject to the Paperwork Reduction Act (PRA) process and approval by the Office of Management and Budget (OMB). The MOON may only be modified as per their accompanying instructions, as well as per guidance in this section. Unapproved modifications cannot be made to the OMB-approved, standardized MOON. The notice and accompanying instructions may be found online at http://www.cms.gov/Medicare/Medicare-General-Information/BNI

400.3.1- Alterations to the MOON (Rev.3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

In general, the MOON must remain two pages, unless inclusion of additional information per section 400.3.8 or State-specific information per section 400.5 below results in additional page(s). Hospitals and CAHs subject to State law observation notice requirements may attach an additional page to the MOON to supplement the "Additional Information" section in order to communicate additional content required under State law, or may attach the notice required under State law to the MOON. The pages of the notice can be two sides of one page or one side of separate pages, but **must not** be condensed to one page.

Hospitals may include their business logo and contact information on the top of the MOON. Text may not be shifted from page 1 to page 2 to accommodate large logos, address headers, or any other information.

400.3.2- Completing the MOON (Rev.3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

Hospitals must use the OMB-approved MOON (CMS-10611). Hospitals must type or write the following information in the corresponding blanks of the MOON:

- Patient name;
- Patient number; and
- Reason patient is an outpatient.

400.3.3– Hospital Delivery of the MOON (Rev.3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

Hospitals and CAHs must deliver the MOON to beneficiaries in accordance with section 400.2 above. Hospitals and CAHs must provide both the standardized written MOON, as well as oral notification.

Oral notification must consist of an explanation of the standardized written MOON. The format of such oral notification is at the discretion of the hospital or CAH, and may include, but is not limited to, a video format. However, a staff person must always be available to answer questions related to the MOON, both in its written and oral delivery formats.

The hospital or CAH must ensure that the beneficiary or representative signs and dates the MOON to demonstrate that the beneficiary or representative received the notice and understands its contents. Use of assistive devices may be used to obtain a signature.

Electronic issuance of the MOON is permitted. If a hospital or CAH elects to issue a MOON viewed on an electronic screen before signing, the beneficiary must be given the option of requesting paper issuance over electronic issuance if that is what the beneficiary prefers. Regardless of whether a paper or electronic

version is issued and regardless of whether the signature is digitally captured or manually penned, the beneficiary must be given a paper copy of the MOON, as specified in 400.3.9, and the required beneficiary specific information inserted, at the time of notice delivery.

400.3.4- Required Delivery Timeframes (Rev.3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

The MOON must be delivered to a beneficiary who receives observation services as an outpatient for more than 24 hours, and must be delivered not later than 36 hours after observation services begin. The MOON must be delivered before 36 hours following initiation of observation services if the beneficiary is transferred, discharged, or admitted. The MOON may be delivered before a beneficiary receives 24 hours of observation services as an outpatient.

The start time of observation services, for purposes of determining when more than 24 hours of observation services have been received, is the clock time observation services are initiated (furnished to the patient), as documented in the patient's medical record, in accordance with a physician's order. This follows the elapsed clock time, rather than the billed time, associated with the observation services.

400.3.5- Refusal to Sign the MOON (Rev.3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

If the beneficiary refuses to sign the MOON, and there is no representative to sign on behalf of the beneficiary, the notice must be signed by the staff member of the hospital or CAH who presented the written notification. The staff member's signature must include the name and title of the staff member, a certification that the notification was presented, and the date and time the notification was presented. The staff member annotates the "Additional Information" section of the MOON to include the staff member's signature and certification of delivery. The date and time of refusal is considered to be the date of notice receipt.

400.3.6– MOON Delivery to Representatives (Rev.3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

The MOON may be delivered to a beneficiary's appointed representative. Appointed representatives are individuals designated by beneficiaries to act on their behalf. A beneficiary may designate an appointed representative via the "Appointment of Representative" form, the CMS-1696. http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/downloads/cms1696.pdf See Chapter 29 of the Medicare Claims Processing Manual, section 270.1, for more information on appointed representatives.

The MOON may also be delivered to an authorized representative. Generally, an authorized representative is an individual who, under State or other applicable law, may make health care decisions on a beneficiary's behalf (e.g., the beneficiary's legal guardian, or someone appointed in accordance with a properly executed durable medical power of attorney).

Notification to a beneficiary who has been deemed legally incompetent is typically made to an authorized representative of the beneficiary. However, if a beneficiary is temporarily incapacitated, a person (typically, a family member or close friend) whom the hospital or CAH has determined could reasonably represent the beneficiary, but who has not been named in any legally binding document, may be a representative for the purpose of receiving the MOON. Such a representative should act in the beneficiary's best interests and in a manner that is protective of the beneficiary and the beneficiary's rights. Therefore, a representative should have no relevant conflict of interest with the beneficiary.

In instances where the notice is delivered to a representative who has not been named in a legally binding document, the hospital or CAH annotates the MOON with the name of the staff person initiating the contact, the name of the person contacted, and the date, time, and method (in person or telephone) of the contact.

<u>Note</u>: There is an exception to the in-person notice delivery requirement. If the MOON must be delivered to a representative who is not physically present to receive delivery of the notice, the hospital or CAH is not required to make an off-site delivery to the representative. The hospital or CAH must complete the MOON as required and telephone the representative.

- The information provided telephonically includes all contents of the MOON;
- Note the date and time the hospital or CAH communicates (or makes a good faith attempt to communicate) this information telephonically, per 400.2 above, to the representative is considered the receipt date of the MOON;
- Annotate the "Additional Information" section to reflect that all of the information indicated above was communicated to the representative; and
- Annotate the "Additional Information" section with the name of the staff person initiating the contact, the name of the representative contacted by phone, the date and time of the telephone contact, and the telephone number called.

Mail a copy of the annotated MOON to the representative the day telephone contact is made.

A hard copy of the MOON must be sent to the representative by certified mail, return receipt requested, or any other delivery method that can provide signed verification of delivery (e.g., FedEx, UPS). The burden is on the hospital or CAH to demonstrate that timely contact was attempted with the representative and that the notice was delivered.

If the hospital or CAH and the representative both agree, the hospital or CAH may send the notice by fax or e-mail; however, the hospital or CAH's fax and e-mail systems must meet the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy and security requirements.

400.3.7 – Ensuring Beneficiary Comprehension (Rev. 3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

The OMB-approved standardized MOON is available in English and Spanish. If the individual receiving the notice is unable to read its written contents and/or comprehend the required oral explanation, hospitals and CAHs must employ their usual procedures to ensure notice comprehension. Usual procedures may include, but are not limited to, the use of translators, interpreters, and assistive technologies. Hospitals and CAHs are reminded that recipients of Federal financial assistance have an independent obligation to provide language assistance services to individuals with limited English proficiency (LEP) consistent with section 1557 of the Affordable Care Act and Title VI of the Civil Rights Act of 1964. In addition, recipients of Federal financial assistance have an independent obligation to provide auxiliary aids and services to individuals with disabilities free of charge, consistent with section 1557 of the Affordable Care Act and section 504 of the Rehabilitation Act of 1973.

400.3.8 - Completing the Additional Information Field of the MOON (Rev.3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

This section may be populated with any additional information a hospital wishes to convey to a beneficiary.

Such information may include, but is not limited to:

- Contact information for specific hospital departments or staff members.
- Additional content required under applicable State law related to notice of observation services.
- Part A cost-sharing responsibilities if a beneficiary is admitted as an inpatient before 36 hours following initiation of observation services.

- The date and time of the inpatient admission if a patient is admitted as an inpatient prior to delivery of the MOON.
- Medicare Accountable Care Organization information.
- Hospital waivers of the beneficiary's responsibility for the cost of self-administered drugs.
- Any other information pertaining to the unique circumstances regarding the particular beneficiary.

If a hospital or CAH wishes to add information that cannot be fully included in the "Additional Information" section, an additional page may be attached to supplement the MOON.

400.3.9- Notice Retention for the MOON (Rev. 3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

The hospital or CAH must retain the original signed MOON in the beneficiary's medical record. The beneficiary receives a paper copy of the MOON that includes all of the required information described in section 400.3.2 and, as applicable, sections 400.3.5, 400.3.6 and 400.3.8. Electronic notice retention is permitted.

400.4- Intersection with State Observation Notices (Rev. 3695, Issued: 01-20-17, Effective: 02-21-17, Implementation: 02-21-17)

As noted in sections 400.3.1 and 400.3.8 above, hospitals and CAHs in States that have State-specific observation notice requirements may add State-required information to the "Additional Information" field, attach an additional page, or attach the notice required under State law to the MOON.