

Health Insurance Portability and Accountability Act (HIPAA) prohibits Medicare (a HIPAA covered entity) from disclosing an individual's protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements. Medicare will make available to Medicare beneficiaries a standard, valid authorization to enable beneficiaries to request the disclosure of their protected health information. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for Medicare. Form CMS-10106, the Medicare Authorization to Disclose Personal Health Information, will be used by Medicare beneficiaries to authorize Medicare to disclose their protected health information to a third party. *Form Number:* CMS-10106 (OMB control number: 0938-0930); *Frequency:* Occasionally; *Affected Public:* Individuals or Households; *Number of Respondents:* 1,298,329; *Total Annual Responses:* 1,298,329; *Total Annual Hours:* 324,582. (For policy questions regarding this collection contact Sam Jenkins at 410-786-3261.)

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Data Use Agreement (DUA) for Data Acquired from the Centers for Medicare & Medicaid Services (CMS); *Use:* The Privacy Act of 1974 allows for discretionary releases of data maintained in Privacy Act protected systems of records under § 552a(b) (Conditions of Disclosure). The mandate to account for disclosures of data under the Privacy Act is found at § 552a(c)(Accounting of Certain Disclosures). This section states that certain information must be maintained regarding disclosures made by each agency. This information is: Date, Nature, Purpose, and Name/Address of Recipient. Section 552a(e) sets the overall requirements that each agency must meet in order to maintain records under the Privacy Act. The Data Use Agreement (DUA) form is needed as part of the review of each CMS data request to ensure compliance with the requirements of the Privacy Act for disclosures that contain personally identifiable information (PII). The DUA form also provides data requestors and custodians with a formal means to agree to the data protection and destruction statutory and regulatory requirements of CMS' PII data. The Health Insurance Portability and Accountability Act (HIPAA) of 1996, § 1173(d) (Security

Standards for Health Information) requires us to protect PII. Additionally, the Federal Information Security Management Act (FISMA) of 2002, § 3544 (b) (Federal Agency Responsibilities—Agency Program) also requires us to develop policies and procedures for the protection and destruction of sensitive data to include PII. We use the information collected by the DUA to track disclosures, conditions for disclosure, accounting of disclosures and agency requirements dictated by the Privacy Act, HIPAA and FISMA.

*Form Number:* CMS-R-235 (OMB control number: 0938-0734); *Frequency:* Annually; *Affected Public:* Private sector—business or other for-profits and not-for-profit institutions; *Number of Respondents:* 9,220; *Total Annual Responses:* 9,220; *Total Annual Hours:* 2,740. (For policy questions regarding this collection contact Sharon Kavanagh at 410-786-5441.)

Dated: June 24, 2014.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

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**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[Document Identifier: CMS-370 and CMS-377, CMS 437, CMS-10510, CMS-216-94, CMS-10494, CMS-10224, CMS-10472 and CMS-10499]

### Agency Information Collection Activities: Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information

collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

**DATES:** Comments on the collection(s) of information must be received by the OMB desk officer by *July 28, 2014*.

**ADDRESSES:** When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395-5806 or, Email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). 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 <http://www.cms.hhs.gov/PaperworkReductionActof1995>.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to [Paperwork@cms.hhs.gov](mailto:Paperwork@cms.hhs.gov).

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

**FOR FURTHER INFORMATION CONTACT:** Reports Clearance Office at (410) 786-1326.

**SUPPLEMENTARY INFORMATION:** Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

### 1. Type of Information Collection

**Request:** Revision of a currently approved collection; **Titles of Information Collection:** Health Insurance Benefits Agreement and Ambulatory Surgical Request for Certification or Update of Certification Information in the Medicare Program; **Use:** The CMS-370 is used to establish eligibility for payment. This agreement, upon submission by the ambulatory surgical center (ASC) and acceptance for filing by the Secretary of Health & Human Services, shall be binding on both the ASC and the Secretary. The agreement may be terminated by either party in accordance with regulations. In the event of termination, payment will not be available for ASC services furnished on or after the effective date of termination. The CMS-377 is used to collect facility-specific characteristics that facilitate CMS' oversight of ambulatory surgical centers. The CMS-377 is submitted by ASCs when they request initial certification of compliance with the ASC conditions for coverage or to update an ASC's existing certification information. It is also used by State agencies who conduct certification surveys on CMS' behalf to maintain information on the facility's characteristics that facilitate conducting surveys, e.g., determining the size and the composition of the survey team on the basis of the number of operating and procedure rooms and the types of surgical procedures performed in the ASC.

**Form Numbers:** CMS-370 and CMS-377 (OMB control number: 0938-0266); **Frequency:** Occasionally; **Affected Public:** Private Sector—Business or other for-profit and Not-for-profit institutions; **Number of Respondents:** 5,449; **Total Annual Responses:** 1,833; **Total Annual Hours:** 633. (For policy questions regarding this collection contact Erin McCoy at 410-786-2337.)

### 2. Type of Information Collection

**Request:** Reinstatement with Change of a currently approved collection; **Title of Information Collection:** Psychiatric Unit Criteria Work Sheet and Supporting Regulations; **Use:** Certain hospital units are excluded from the Medicare Prospective Payment System (PPS). The exclusion of units is not optional on the part of the provider but is required by section 1886(d)(1)(B) of the Social Security Act. That section excludes psychiatric hospitals, rehabilitation hospitals, hospitals whose inpatients are predominantly individuals under 18 years of age (children's hospitals), and psychiatric and rehabilitation units which are a distinct part of a hospital. We propose to continue the current process of performing initial

verifications and annual re-verifications to determine that psychiatric units continue to comply with the regulatory criteria at 42 CFR 412.25 and 42 CFR 412.27 of the PPS regulations. These regulations state the criteria that distinct part units must meet for exclusion.

If, as a result of the regular survey process a hospital is certified as a psychiatric hospital by the State survey agency (SA), then it automatically satisfies the regulatory criteria for exclusion. Thus, no additional verification is required for psychiatric hospitals. Some verification is needed, however, to ensure that other types of hospitals and units meet the criteria for exclusion. Consequently, we instructed the Medicare Administrative Contractors (MACs) (formerly known as FIs) and SAs to perform certain verification activities, beginning in October 1983 when PPS was implemented. We originally developed the CMS-437 as an SA Worksheet for verifying exclusions from PPS for psychiatric units.

Since April 9, 1994, PPS-excluded psychiatric units already excluded from the PPS have met our annual requirement for PPS-exclusion by self-attesting that they remain in compliance with the PPS exclusion criteria. Under the current procedure, all psychiatric units applying for first-time exclusion are surveyed by the SAs. The SAs also perform surveys to investigate complaint allegations and conduct annual sample re-verification surveys on 5 percent of all psychiatric units. The aforementioned exclusions continue to exist and thus we propose to continue to use the Criteria Worksheet, Forms CMS-437, for verifying first-time exclusions from the PPS, for complaint surveys, for its annual 5 percent validation sample, and for facility self-attestation. These forms are related to the survey and certification and Medicare approval of the PPS-excluded units.

**Form Number:** CMS-437 (OMB control number: 0938-0358); **Frequency:** Annually; **Affected Public:** Private sector—Business or other for-profits; **Number of Respondents:** 1,614; **Total Annual Responses:** 1,614; **Total Annual Hours:** 404. (For policy questions regarding this collection contact Donald Howard at 410-786-6764.)

### 3. Type of Information Collection

**Request:** Extension of a currently approved collection; **Title of Information Collection:** Basic Health Program Report for Health Insurance Exchange Premium; **Use:** The Basic Health Program (BHP) is federally funded by determining the amount of payments that the federal government

would have made through the premium tax credit (PTC) and cost sharing reductions (CSR) for people enrolled in BHP had they instead been enrolled in an Exchange. To calculate the amounts for each state, we need the reference premiums for the second lowest cost silver plans (SLCSP) in each geographic area in a state, as SLCSPs are a basic unit in the calculation of PTC and CSRs under the Exchanges. To estimate what PTC and CSRs would have been paid, the reference premiums for these SLCSPs are critical components in the BHP payment methodology. Similarly, we also need to collect reference premiums for the lowest cost bronze plans to appropriately account for CSR calculations for American Indians and Alaskan Natives. Reference premiums are foundational inputs into the BHP payment methodology. We have the necessary information to determine these reference premiums for states with Exchanges operated by the Federally Facilitated Exchange (FFE) or are operated in partnership with the FFE. Consequently, this collection only pertains to the 17 states that are operating State Based Exchanges.

**Form Number:** CMS-10510 (OMB control number: 0938-1218); **Frequency:** Yearly; **Affected Public:** State, Local, or Tribal Governments; **Number of Respondents:** 17; **Total Annual Responses:** 17; **Total Annual Hours:** 68. (For policy questions regarding this collection contact Carey Appold at 410-786-2117).

### 4. Type of Information Collection

**Request:** Extension of a currently approved collection; **Title of Information Collection:** Organ Procurement Organization/ Histocompatibility Laboratory Cost Report; **Use:** We are requesting an extension of the Form CMS 216-94, Organ Procurement Organization (OPO)/ Histocompatibility Laboratory Cost Report. These cost reports are filed annually by freestanding OPO and Histocompatibility Lab providers participating in the Medicare program to determine the reasonable costs incurred to furnish treatment for renal transplant patients. **Form Number:** CMS-216-94 (OMB control number: 0938-0102); **Frequency:** Annually; **Affected Public:** Private sector—Business or other for-profits; **Number of Respondents:** 107; **Total Annual Responses:** 107 **Total Annual Hours:** 4,815. (For policy questions regarding this collection contact Angela Havrilla at 410-786-4516.)

### 5. Type of Information Collection

**Request:** Revision of a previously approved information collection; **Title of Information Collection:** Consumer

Assistance Tools and Programs of an Exchange and Certified Application Counselors; Exchange and Insurance Market Standards for 2015; *Use*: Section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations establishing the certified application counselor program are being finalized at 45 CFR 155.225. Specifically, 45 CFR 155.225(a) requires an Exchange to establish a certified application counselor program that complies with the requirements of the rule. Section 155.225(b)(1) allows each Exchange to designate certain organizations, including organizations designated by state Medicaid or CHIP agencies, which will certify their staff and volunteers to act as certified application counselors. In accordance with 45 CFR 155.225(b)(2), Exchanges may choose to certify directly individuals who seek to act as certified application counselors, designate certain organizations which will certify staff or volunteers to perform application services, or do both. In accordance with 155.225(d)(7), certified application counselors in all Exchanges are required to be recertified on at least an annual basis and successfully complete Exchange-required recertification training.

*Form Number*: CMS-10494 (OMB control number: 0938-1205); *Frequency*: On Occasion; *Affected Public*: State, Local, or Tribal Governments, Private Sector; not-for-profit institutions; individuals or households; *Number of Respondents*: 35,000; *Number of Responses*: 160,000; *Total Annual Hours*: 19,610. (For policy questions regarding this collection, contact Tricia Beckmann at 301-492-4328.)

**6. Type of Information Collection**  
*Request*: Extension of a currently approved collection; *Title of Information Collection*: Healthcare Common Procedure Coding System (HCPCS)—Level II Code Modification Request Process; *Use*: Each year in the United States healthcare insurers process over 5 billion claims for payment. For Medicare and other health insurance programs to ensure that these claims are processed in an orderly and consistent manner, standardized coding systems are essential. The Healthcare Common Procedure Coding System (HCPCS) Level II Code Set is one of the standard code sets used for this purpose. Level II of the HCPCS, also referred to as alpha-numeric codes, is a standardized coding system that is used

primarily to identify products, supplies, and services not included in the CPT codes, such as ambulatory services and durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) when used in the home or outpatient setting.

The HCPCS codeset has been maintained and distributed via modifications of codes, modifiers and descriptions, as a direct result of data received from applicants. The HCPCS codeset maintenance is an ongoing process, as changes are implemented and updated annually; therefore, the process requires continual collection of information from applicants on an annual basis. As new technology evolves and new devices, drugs and supplies are introduced to the market, applicants submit applications to us requesting modifications to the HCPCS Level II codeset.

*Form Number*: CMS-10224 (OMB control number: 0938-1042); *Frequency*: Annually; *Affected Public*: Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents*: 300; *Total Annual Responses*: 300 *Total Annual Hours*: 3,300. (For policy questions regarding this collection contact Kimberlee Combs Miller at 410-786-6707.)

**7. Type of Information Collection**  
*Request*: Revision of a previously approved information collection; *Title of Information Collection*: Exchange Functions: Standards for Navigators and Non-Navigator Assistance Personnel; *Use*: Section 1321(a)(1) of the Affordable Care Act directs and authorizes the Secretary to issue regulations setting standards for meeting the requirements under title I of the Affordable Care Act, with respect to, among other things, the establishment and operation of Exchanges. Pursuant to this authority, regulations have been finalized at 45 CFR 155.210(e)(6) and 45 CFR 155.215(g) to require Navigators, as well as those non-Navigator personnel to whom 45 CFR 155.215 applies, to inform consumers of the functions and responsibilities of Navigators and non-Navigator assistance personnel (as applicable) and obtain authorization for the disclosure of consumer information to the Navigator or non-Navigator assistance personnel prior to obtaining the consumer's personally identifiable information. Navigators and non-Navigator assistance personnel to whom 45 CFR 155.215 applies are also required to maintain a record of the authorization provided in a form and manner as determined by the Exchange.

*Form Number*: CMS-10472 (OMB control number: 0938-1220); *Frequency*: On Occasion; *Affected Public*: State, Local, or Tribal Governments, Private

Sector (not-for-profit institutions); individuals or households; *Number of Respondents*: 5,610; *Number of Responses*: 5,610; *Total Annual Hours*: 35,709. (For policy questions regarding this collection, contact Emily Ames at 301-492-4246.)

**8. Type of Information Collection**  
*Request*: New collection (Request for a new OMB control number); *Title of Information Collection*: Public Health Agency/Registry Readiness to Support Meaningful Use; *Use*: The Medicare and Medicaid Electronic Health Record (EHR) Incentive Programs provide incentives for the meaningful use of Certified Electronic Health Record Technology (CEHRT). We defined meaningful use as a set of objectives and measures in either Stage 1 or Stage 2 depending on how long an eligible provider has participated in the program. Both Stage 1 (3 objectives) and Stage 2 (5 objectives) of meaningful use contain objectives and measures that require eligible providers to determine the readiness of public health agencies and registries to receive electronic data from CEHRT. Public comments on the notice of proposed rulemaking for Stage 2 of meaningful use (77 FR 13697) asserted that the burden for each individual eligible provider to determine the readiness of multiple public health agencies and registries could be nearly eliminated if we were to maintain a database on the readiness of public health agencies and registries. In the final rule for Stage 2 of meaningful use (77 FR 53967), we agreed that the burden on eligible providers, public health agencies and registries would be greatly reduced and established that we would create such a database and it would serve as the definitive information source for determining public health agency and registry readiness to receive electronic data associated with the public health meaningful use objectives. The information will be made publicly available on the CMS Web site ([www.cms.gov/EHRincentiveprograms](http://www.cms.gov/EHRincentiveprograms)) in order to provide a centralized repository of this information to eligible providers and eliminate there multiple individual inquiries to multiple public health agencies and registries. *Form Number*: CMS-10499 (OMB control number: 0938-New); *Frequency*: Yearly; *Affected Public*: Private sector—Business or other for-profits and Not-for-profit institutions; *Number of Respondents*: 250; *Total Annual Responses*: 250; *Total Annual Hours*: 83. (For policy questions regarding this collection contact Kathleen Connors de Laguna at 410-786-2256.)

Dated: June 24, 2014.

**Martique Jones,**

*Deputy Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.*

[FR Doc. 2014-15073 Filed 6-26-14; 8:45 am]

BILLING CODE 4120-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-3301-PN]

#### Medicare and Medicaid Programs; Application From Det Norske Veritas Healthcare for Continued CMS-Approval of Its Critical Access Hospital Accreditation Program

**AGENCY:** Centers for Medicare and Medicaid Services, HHS.

**ACTION:** Proposed notice.

**SUMMARY:** This proposed notice acknowledges the receipt of an application from Det Norske Veritas Healthcare (DNVHC) for continued recognition as a national accrediting organization for critical access hospitals (CAHs) that wish to participate in the Medicare or Medicaid programs.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on July 28, 2014.

**ADDRESSES:** In commenting, please refer to file code CMS-3301-PN. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways:

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.regulations.gov>. Follow the "submit a comment" instructions.

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3301-PN, P.O. Box 8016, Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3301-PN, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* Alternatively, you may deliver (by hand or courier) your written comments to the following addresses:

a. For delivery in Washington, DC—Centers for Medicare & Medicaid Services, Department of Health and Human Services, Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without federal government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments erroneously mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

b. For delivery in Baltimore, MD—Centers for Medicare & Medicaid Services, Department of Health and Human Services, 7500 Security Boulevard, Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**FOR FURTHER INFORMATION CONTACT:** Barbara Easterling, (410) 786-0482, Cindy Melanson, (410) 786-0310, Patricia Chmielewski, (410) 786-6899, or Lillian Williams, (410) 786-8636.

#### **SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on all issues set forth in this proposed notice to assist us in fully considering issues and developing policies. Referencing the file code CMS-3301-PN and the specific "issue identifier" that precedes the section on which you choose to comment will assist us in fully considering issues and developing policies.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.regulations.gov>. Follow the search

instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

#### **I. Background**

Under the Medicare program, eligible beneficiaries may receive covered services in a Critical Access Hospital (CAH) provided certain requirements are met by the CAH. Section 1820(e) and 1861(mm) of the Social Security Act (the Act), establishes distinct criteria for facilities seeking designation as a CAH. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of facilities are at 42 CFR part 488. The regulations at 42 CFR part 485, subpart F specify the conditions that a CAH must meet to participate in the Medicare program, the scope of covered services, and the conditions for Medicare payment for CAHs.

Generally, to enter into an agreement, a CAH must first be certified by a state survey agency as complying with the conditions or requirements set forth in part 485, subpart F of our CMS regulations. Thereafter, the CAH is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements. There is an alternative, however, to surveys by state agencies.

Section 1865(a)(1) of the Act provides that, if a provider entity demonstrates through accreditation by an approved national accrediting organization that all applicable Medicare conditions are met or exceeded, we will deem those provider entities as having met the requirements. Accreditation by an accrediting organization is voluntary and is not required for Medicare participation.

If an accrediting organization is recognized by the Secretary as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting body's approved program would be deemed to meet the Medicare conditions. A national accrediting organization applying for approval of its accreditation program under part 488, subpart A, must provide us with reasonable assurance that the