

police departments, sheriff's departments, or similar governmental organizations throughout the continental United States. One thousand five LEO volunteers will participate in

the study over three years, with a study goal of obtaining complete anthropometric assessment of 1,000 LEOs. Information collection for each respondent is expected to take no longer

than 63 minutes (total) to complete. Participation is voluntary and there are no costs to the respondents other than their time. The total estimated annualized burden hours are 353.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Law Enforcement Officers	Biographical Information	335	1	3/60
Law Enforcement Officers	Data Sheet	335	1	25/60
Law Enforcement Officers	Assessment of Challenges in Vehicle and with Body Armor.	335	1	5/60
Law Enforcement Officers	Two-dimensional Hand Scan and Three-dimensional Body Scans.	335	1	30/60

Leroy Richardson,

Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-3349-FN]

Medicare and Medicaid Programs; Approval of the Community Health Accreditation Partner for Continued CMS Approval of Its Home Health Agency Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces our decision to approve the Community Health Accreditation Partner (CHAP) for continued recognition as a national accrediting organization for home health agencies (HHAs) that wish to participate in the Medicare or Medicaid programs.

DATES: This notice is applicable March 31, 2018 through March 31, 2024.

FOR FURTHER INFORMATION CONTACT: Lillian Williams (410) 786-8636, Monda Shaver, (410) 786-3410, or Patricia Chmielewski (410) 786-6899.

SUPPLEMENTARY INFORMATION:

I. Background

Under the Medicare program, eligible beneficiaries may receive covered services from a home health agency (HHA) provided certain requirements are met. Sections 1861(m) and (o), 1891, and 1895 of the Social Security Act (the

Act) establish distinct criteria for entities seeking designation as an HHA. Regulations concerning provider agreements are at 42 CFR part 489 and those pertaining to activities relating to the survey and certification of agencies and other entities are at 42 CFR part 488. The regulations at 42 CFR parts 409 and 484 specify the conditions that an HHA must meet to participate in the Medicare program, the scope of covered services and the conditions for Medicare payment for home health care.

Generally, to enter into a provider agreement with the Medicare program, an HHA must first be certified by a state survey agency as complying with conditions or requirements set forth in part 484 of our regulations. Thereafter, the HHA is subject to regular surveys by a state survey agency to determine whether it continues to meet these requirements.

However, there is an alternative 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 of Health and Human Services as having standards for accreditation that meet or exceed Medicare requirements, any provider entity accredited by the national accrediting organization's approved program may be deemed to meet the Medicare conditions. A national accrediting organization applying for CMS approval of their accreditation program under 42 CFR part 488, subpart A, must provide CMS

with reasonable assurance that the accrediting organization requires the accredited provider entities to meet requirements that are at least as stringent as the Medicare conditions. Our regulations concerning the approval of accrediting organizations are set forth at § 488.5. Section 488.5(e)(2)(i) requires accrediting organizations to reapply for continued approval of its Medicare accreditation program every 6 years or sooner as determined by CMS. The Community Health Accreditation Partner's (CHAP'S) term of approval as a recognized accreditation program for HHAs expires March 31, 2018.

II. Approval of Accreditation Organizations

Section 1865(a)(3)(A) of the Act provides a statutory timetable to ensure that our review of applications for CMS approval of an accreditation program is conducted in a timely manner. The Act provides us 210 days after the date of receipt of a complete application, with any documentation necessary to make the determination, to complete our survey activities and application process. Within 60 days of receiving a completed application, we must publish a notice in the **Federal Register** that identifies the national accrediting body making the request, describes the request, and provides no less than a 30-day public comment period. At the end of the 210-day period, we must publish a notice in the **Federal Register** approving or denying the application.

III. Proposed Notice

On October 20, 2017, we published a proposed notice in the **Federal Register** (82 FR 48817) announcing CHAP's request for continued approval of its Medicare HHA accreditation program. In the proposed notice, we detailed our evaluation criteria. Under section 1865(a)(2) of the Act and § 488.5, we

conducted a review of CHAP's Medicare HHA application in accordance with the criteria specified by our regulations, which include, but are not limited to the following:

- An onsite administrative review of CHAP's: (1) Corporate policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against HHAs; and (5) survey review and decision-making process for accreditation;

- A comparison of CHAP's HHA accreditation standards to our current Medicare HHA conditions for participation (CoPs);

- A documentation review of CHAP's survey processes to:

- ++ Determine the composition of the survey team, surveyor qualifications, and CHAP's ability to provide continuing surveyor training.

- ++ Compare CHAP's processes to those we require of state survey agencies, including periodic resurvey and the ability to investigate and respond appropriately to complaints against accredited HHAs.

- ++ Evaluate CHAP's procedures for monitoring HHAs found to be out of compliance with CHAP program requirements. This pertains only to monitoring procedures when CHAP identifies non-compliance. If non-compliance is identified by a state survey agency through a validation survey, the state survey agency monitors corrections as specified at § 488.9(c)➤

- ++ Assess CHAP's ability to report deficiencies to the surveyed HHAs and respond to the HHA's plan of correction in a timely manner.

- ++ Establish CHAP's ability to provide CMS with electronic data and reports necessary for effective validation and assessment of the organization's survey process.

- ++ Determine the adequacy of CHAP's staff and other resources.

- ++ Confirm CHAP's ability to provide adequate funding for the completion of required surveys.

- ++ Confirm CHAP's policies for surveys being unannounced.

- ++ Obtain CHAP's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(a)(3)(A) of the Act, the October 20, 2017 proposed notice (82 FR 48817) also solicited public comments regarding whether CHAP's requirements met or

exceeded the Medicare CoPs for HHAs. There were no comments submitted.

IV. Provisions of the Final Notice

A. Differences Between CHAP's Standards and Requirements for Accreditation and Medicare Conditions of Participation and Survey Requirements

We compared CHAP's accreditation requirements for HHAs and its survey process with the Medicare CoPs at 42 CFR part 484, and the survey and certification process requirements of 42 CFR parts 488 and 489. CHAP's standards crosswalk, which crosswalks CHAP standards to the corresponding Medicare requirements and regulations, was also examined to ensure that the appropriate CMS regulation would be included in citations as appropriate. Our review and evaluation of CHAP's HHA application, which were conducted as described in section III. of this final notice, yielded the following areas where, as of the date of this notice, CHAP has revised its survey processes so that its processes are comparable to CMS requirements:

- § 488.5(a)(4)(vii), to ensure plans of corrections (PoCs) address all non-compliant practices and include policy changes required to correct the deficient practice.

- § 488.5(a)(7) through (9), to ensure surveyors maintain current licensure, that new surveyors receive the minimum number of mentored surveys prior to surveying independently, and that all new surveyors receive a 90-day evaluation of performance.

- § 488.5(a)(12), to ensure the appropriate number of medical records are reviewed during complaint investigations.

- § 488.26(b), to ensure that survey documentation includes a detailed deficiency statement that clearly outlines the number of medical records reviewed, describes the manner and degree of non-compliance, and supports the appropriate level of deficiency citation.

B. Term of Approval

Based on the review and observations described in section III. of this final notice, we have determined that CHAP's requirements for HHAs meet or exceed our requirements. Therefore, we approve CHAP as a national accreditation organization for HHAs that request participation in the Medicare program, effective March 31, 2018 through March 31, 2024.

V. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, record keeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

Dated: March 8, 2018.

Seema Verma,

Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2397-FN]

RIN-0938-ZB29

Medicaid Program; Announcement of Medicaid Drug Rebate Program National Rebate Agreement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final notice.

SUMMARY: This final notice announces changes to the Medicaid National Drug Rebate Agreement (NDRA, or Agreement) for use by the Secretary of the Department of Health and Human Services (HHS) and manufacturers under the Medicaid Drug Rebate Program (MDRP). We are updating the NDRA to incorporate legislative and regulatory changes that have occurred since the Agreement was published in the February 21, 1991 **Federal Register** (56 FR 7049). We are also updating the NDRA to make editorial and structural revisions, such as references to the updated Office of Management and Budget (OMB)-approved data collection forms and electronic data reporting.

DATES:

Applicability Date: The updated National Medicaid Drug Rebate Agreement (NDRA) provided in the Addendum to this final notice will be applicable on March 23, 2018.

Compliance Date: Publication of CMS-2397-FN serves as written notice of good cause to terminate all existing rebate agreements as of the first day of the full calendar quarter which begins at least 6 months after the effective date of the updated NDRA (October 1, 2018). Manufacturers with an existing active