Supporting Statement for Religious Nonmedical Health Care Institutions (RNHCIs) Conditions of Participation and Supporting Regulations (CMS-10712)

A. Background

The purpose of this package is to request Office of Management and Budget (OMB) approval of the collection of information requirements for the reform of the requirements for RNHCIs. RNHCI facilities are required to meet these requirements in order to participate in the Medicare and Medicaid Programs.

According to Centers for Medicare & Medicaid Services (CMS) data, as of July 2019, there were 16 RNHCIs in the United States. RNHCI facilities include those facilities as defined in section 1861(ss)(1) of the Social Security Act (hereinafter referred to as the Act) defines the term "Religious Nonmedical Health Care Institution" (RNHCI) and lists the requirements that a RNHCI must meet to be eligible for Medicare participation. In section 1861(ss)(1) of the Act the term religious nonmedical health care institution means an institution that provides only nonmedical nursing items and services exclusively to patients who choose to rely solely upon a religious method of healing and for whom the acceptance of medical health services would be inconsistent with their religious beliefs.

Section 403.736(a) and (b) of the RNHCI's conditions of participation (CoPs), as amended in the November 28, 2003 **Federal Register** (68 FR 66710), requires RNHCIs to have a discharge planning process for patients.

B. JUSTIFICATION

1. Need and Legal Basis

The information collection requirements for which we are requesting OMB approval are listed below. These requirements are among other requirements which are based on criteria prescribed in law and regulations designed to ensure that each RNHCI facility safely and effectively delivers care to its patients. The information collections requirements described herein are needed to implement these nonmedical health care requirements for all RNHCI facilities. We believe many of the requirements applied to these facilities will impose no burden since a prudent institution will self-impose them in the course of doing business.

The regulations containing these information collection requirements are located at 42 CFR 403 Subpart G and they implement section 1861(ss)(1) of the Act. Section 1861(e) of the Act authorizes promulgation of regulations in the interest of the health and safety of individuals who are furnished services by a RNHCI. The Secretary may impose additional requirements if they are necessary in the interest of the health and safety of the individuals who are furnished services in the RNHCI.

Statutory requirements and our responsibility to assure an adequate level of patient health and safety in participating RNHCI require the inclusion of these requirements in the CoPs. These requirements are based on criteria prescribed in law and are standards designed to ensure that each RNHCI facility safely and effectively delivers care to all residents. The information collection requirements described herein are needed to implement these health and safety standards requirements for all Medicare and Medicaid participating RNHCI facilities

The information collection requirements are located at 42 CFR 403 Subpart G and implement section 1861(ss)(1) of the Act.

2. Information Users

The primary users of this information will be State agency surveyors, CMS, and the RNHCI facilities for the purposes of ensuring compliance with Medicare and Medicaid requirements as well as ensuring the quality of care provided to RHNCI patients. Surveyors will use the CoP requirements to evaluate compliance with The ICRs specified in the regulations may be used as a basis for determining whether a RNHCI is meeting the requirements to participate in the Medicare program.

3. Use of Information Technology

RNHCIs may use various information technologies to store and manage patient medical records as long as they are consistent with statutory and regulatory requirements for record keeping and confidentiality. Use of certified health information technologies (HIT) is encouraged but not required, as some facilities, particularly small or rural facilities, may not have electronic capacity at this time. Facilities are free to take advantage of any technology advances they find appropriate for their needs.

4. Duplication of Efforts

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

These requirements do affect small businesses. However, the general nature of the requirements allows facilities the flexibility to meet the requirements in ways that are consistent with their existing operations.

6. Less Frequent Collection

CMS does not collect this information, or require its collection on a routine basis. Nor does the rule prescribe the manner, timing, or frequency of the records or information required to be available. CAH records are reviewed at the time of a survey for initial

or continued participation in the Medicare program. Less frequent information collection would impede efforts to establish compliance with the Medicare CoPs.

7. Special Circumstances

There are no special circumstances.

8. Federal Register Notice/Outside Consultation

A 60-day Federal Register notice of the Burden Reduction Proposed Rule (83 FR 47686) published on September 20, 2018.

9. Payment/Gift To Respondents

There are no payments/gifts to respondents.

10. Confidentiality

We pledge confidentiality of patient-specific data in accordance with the Privacy Act of 1974 (5 U.S.C. 552a).

11. Sensitive Questions

There are no questions of a sensitive nature associated with this information collection.

12. Burden Estimates (Hours & Wages)

We believe many of the requirements applied to these facilities will impose no burden since a prudent institution will self-impose them in the course of doing business.

In analyzing information collection costs, we rely heavily on wage and salary information. Unless otherwise indicated, we obtained all salary information from the May 2018 National Occupational Employment and Wage Estimates by the Bureau of Labor Statistics (BLS) at https://www.bls.gov/oes/current/oes_nat.htm. Based on this information we have calculated the estimated hourly costs based upon the national mean hourly wage for each particular position, increased by 100 percent to account for overhead costs and fringe benefits.

The table that follows presents the BLS occupation code and titles used for our estimates, the mean hourly wage of each position, and the adjusted hourly wage (with a 100 percent markup of the salary to include costs of fringe benefits and overhead).

TABLE 1—SUMMARY INFORMATION OF ESTIMATED HOURLY WAGES

Occupation Code	BLS Occupation	Mean Hourly Wage	Total Hourly Cost

	Title		(Including overhead and fringe benefit costs, rounded to nearest dollar)
31-9099	Healthcare Support Workers	$18.80	** Expression is faulty **
43-9061	Office Clerks, General	$16.92	** Expression is faulty **
11-9199	Managers, All Other	$55.57	** Expression is faulty **
29-2061	Licensed Practical and Licensed Vocational Nurses	$22.62	** Expression is faulty **

§403.724 Valid election requirements

RNHCIs are required to have beneficiaries or his or her legal representative sign an election statement. The election must be a written statement that includes the following statements:

- The beneficiary is conscientiously opposed to acceptance of nonexcepted medical treatment.
- The beneficiary acknowledges that the acceptance of nonexcepted medical treatment is inconsistent with his or her sincere religious beliefs.
- The beneficiary acknowledges that the receipt of nonexcepted medical treatment constitutes a revocation of the election and may limit further receipt of services in an RNHCI.
- The beneficiary acknowledges that the election may be revoked by submitting a written statement to CMS.
- The beneficiary acknowledges that revocation of the election will not prevent or delay access to medical services available under Medicare Part A in facilities other than RNHCIs.

The one-time burden of developing these election statements has already been incurred by all 16 facilities, and we believe any further costs of development would not subject to the PRA in accordance with 5 CFR 1320.3(c)(4) because this is not expected to affect 10 or more facilities in any given year.

Section 403.724(a)(2) and § 403.724(a)(3) Require the election form to be signed and dated by the beneficiary or his or her legal representative and notarized. The RNHCI must keep a copy of the election statement on file.

The burden associated with this requirement is the time required for the beneficiary or his or her legal representative to read, sign, and date the election statement and have it notarized. It is estimated that it will take each beneficiary approximately 10 minutes to read, sign, and date the election statement. We anticipate that the RNHCI will have a notary present to witness and notarize the election statement. We estimate there are

approximately 619 beneficiaries that will be affected by this requirement for a total of 103 burden hours annually. For all facilities combined, this comes to an annual cost of $3,502 ($34/hour for an office clerk x 103 hours).

Section 403.724(a)(4) requires that the RNHCI keep a copy of the election statement on file and submit the original to CMS with any information obtained regarding prior elections or revocations. The burden associated with this requirement is the time required for an RNHCI to keep a copy of the election statement and submit the original to CMS. Based on our experience with RNHCI providers and other Medicare and Medicare providers/suppliers performing such tasks, it is estimated that it will take 5 minutes for a clerical staff to comply with this requirement. Based on the number of beneficiaries discharged annually (619), we assume there will be approximately 619 election statements annually for a total of 52 burden hours. For all facilities combined, this comes to an annual cost of $1,768 ($34/hour for an office clerk x 52 hours).

Section 403.724(b)(1) states that a beneficiary can revoke his or her election statement by the receipt of nonexcepted medical treatment or the beneficiary may voluntarily revoke the election and notify CMS in writing. We anticipate that there would be very few (fewer than 10 beneficiaries) if any instances in which a beneficiary will notify CMS in writing that he or she will revoke his or her election statement. We believe the above requirement is not subject to the PRA in accordance with 5 CFR 1320.3(c)(4) since this requirement does not collect information from 10 or more entities on an annual basis.

§403.730(a) *Notice of rights*

A RNHCI must protect and promote each patient's rights. §403.730(a) requires the RNHCI to inform each patient of his or her rights in advance of furnishing patient care.

Each RNHCI must have a process for prompt resolution of grievances, including a specific person within the facility whom a patient may contact to file a grievance. In addition, the facility must provide patients with information about the facility's process as well as with contact information for appropriate State and Federal resources. The burden associated with this activity is the time it would take for each patient to be informed of their rights and informed of the grievance process and contact information for state and federal resources. Based on our experience with RNHCIs and other providers with similar requirements, we estimate this requires 20 minutes per patient which is 206 annual burden hours (0.3333 hours x 619 beneficiaries). We anticipate that a member of the nonmedical nursing staff would perform these duties. For all facilities combined, this comes to an annual cost of $7,828 ($38 x 206 hours).

§403.730(d)(2) *Confidentiality of patient records*

Maintain the confidentiality of patient records in an accurate manner.

We are not including burden associated with certain patient related activities such as healthcare plans, patient records, clinical records, etc., because prudent institutions would

incur this burden in the course of doing everyday business. As stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2), the burden associated with usual and customary business practices is exempt. Further, State laws require providers to maintain patient records. (For example, the annotated Code of Maryland (¶ 10.11.03.13) requires a provider to be responsible for maintaining patient records for services that it provides.) State law also requires record information that should include: documentation of personal interviews; diagnosis and treatment recommendations; records of professional visits and consultations; consultant notes which shall be appropriately initialed or signed. In accordance with 5 CFR 1320.3(b)(3), a collection of information conducted or sponsored by a Federal agency that is also conducted or sponsored by a unit of State, local, or tribal government is presumed to impose a Federal burden except to the extent that the agency shows that such State, local, or tribal requirement would be imposed even in the absence of a Federal requirement.

§403.732 Condition of participation: Quality assessment and performance improvement.

The existing regulations require a RNHCI to develop, implement, and maintain a quality assessment and performance improvement program. A facility must inform all patients, in writing, of the scope and responsibilities of the quality assessment and performance improvement program. The facility must act to make performance improvements and must track performance to assure that improvements are sustained.

The annual burden associated with this requirement is for a RNHCI to develop and maintain the necessary documentations of its QAPI program and to inform patients in writing of the scope and responsibilities of the QAPI program. We estimate that it would take the administrator (11-9199), nonmedical director (29-2061), and a clerical staff worker (43-9061) approximately 3 hours quarterly (or 1 hour each), for a total of 12 hours annually, to compile the results of the program. This is a total annual cost of $760 per facility (($111/hour for an administrator + $45/hour for a nonmedical director + $34/hour for a clerical worker) x 4 quarters). It would also take a total of 96 hours (estimating that it would take each RNHCI's nonmedical director 6 hours annually for the 16 facilities) to inform all patients in writing of the QAPI program, which is a total annual cost of $270 per facility ($45/hour for a nonmedical director x 6 hours). Therefore, for all 16 facilities this constitutes an annual burden of approximately 288 hours ((12 hours + 6 hours) x 16 facilities) and $16,480 (($760 + $270) x 16 facilities).

§403.736 Discharge Planning

§403.736(a) and §403.736(b) require each RNHCI to have in effect a discharge planning process that applies to all patients. The process must assure that appropriate post-institution services are obtained for each patient, as necessary. The RNHCI must assess the need for a discharge plan for any patient identified as likely to suffer adverse consequences if there is no planning and for any other patient upon his or her request or at the request of his or her legal representative. This discharge planning evaluation must be initiated at admission and must include an assessment of the possibility of a patient needing post-RNHCI services and of the availability of those services. An assessment

must be made of the probability of a patient's capacity for self-care or of the possibility of the patient being cared for in the environment from which he or she entered the RNHCI.

The staff must complete the assessment on a timely basis so that arrangements for post-RNHCI care are made before discharge and so that unnecessary delays in discharge are avoided. The discharge planning evaluation must be included in the patient's care record for use in establishing an appropriate discharge plan. Staff must discuss the results of the discharge planning evaluation with the patient or a legal representative acting on his or her behalf. If the discharge planning evaluation indicates a need for a discharge plan, qualified and experienced personnel must develop or supervise the development of the plan.

We estimate that the healthcare support worker responsible for a patients discharge plan costs $38 an hour, including hourly wage and an estimated 100 percent add-on for fringe benefit costs and overhead costs. Based on our experience with RNHCIs, we estimate that it takes 2 hours to develop the discharge instructions and discuss them with the patient or caregiver. Therefore, we estimate that the time required to develop and document discharge plans and activities is 1,238 burden hours (2 hours for each of the 619 beneficiaries discharged) at a cost of $47,044 ($38/hour for a healthcare support worker x 1,238)

§403.736(d) requires each RNHCI reassess its discharge planning process on an ongoing basis. We estimate that each facility would conduct an annual review of the discharge planning process. The reassessment must include a review of discharge plans to ensure that they are responsive to discharge needs. We estimate that it would take the RNHCI's administrator (11-9199), nonmedical director (29-2061), and a nonmedical nursing staff (31-9099) one hour each to reassess its discharge planning process and make any necessary changes which would be 48 hours (3 hours x 16 facilities). We further estimate that it would take a clerical staff worker 30 minutes to document the necessary changes which would be 8 hours (.5 x). This is an annual burden of 3.5 hours or $211 per facility (($111/hour for an administrator + $45/hour for a nonmedical director + $38/hour for nonmedical nursing staff) + ($34/hour for a clerical worker x 0.5 hours)), or 56 hours and $3,376 for all 16 RNHCIs.

The table below summarizes the estimated annual reporting and recordkeeping burden.

TABLE 2—ANNUAL REPORTING AND RECORDKEEPING BURDENS

Regulation Section(s)	**Number of Respondents**	**Number of Responses**	**Burden per Response (hours)**	**Total Annual Burden (hours)**	**Total Annual Cost ($)**
§403.724(a)	16	619	0.25	155	$5,270
§403.730(a)	16	619	0.3333	206	$7,828
§403.732	16	16	18	288	$16,480

§403.736(a)(b)	16	619	2	1,238	$47,044
§403.736(d)	16	16	3.5	56	$3,376
Totals		**0**		0	0

13. Capital Costs

There are no capital costs.

14. Cost To Federal Government

Although the Federal Government does not collect this information, there are minimal costs associated with these requirements that are accrued at the Federal level and especially at the regional office (RO) levels. For example, RO staff is responsible for acting on the information collections requirements discussed in this package as it relates to RNHCI compliance. Once state survey agencies have completed their surveys and if an initial determination to terminate a RNHCI for noncompliance is to be made, such decisions are made by the RO. Each RNHCI is surveyed once every 3 years, so we estimate this would require 4 hours of a Health Insurance Specialist GS-13 earning approximately $53 per hour depending on locality adjustments ($106 including fringe benefit and overhead costs) every 3 years per RNHCI. This comes to a total cost of $6,784 ($106/hour x 4 hours x 16 RNHCIs), or an annualized cost of $2,261.

15. Adjustments/ Program Changes

This is a new information collection..

16. Publication/Tabulation Dates

We do not plan to publish any of the information collected.

17. Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.

18. Certification

There are no exceptions to the certification statement.