DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality

Admin Info: 21-03-ALL

DATE:	**January 8, 2021**
TO:	State Survey Agency Directors
FROM:	Directors, Quality, Safety & Oversight Group and Survey Operations Group
SUBJECT:	Fiscal Year (FY) 2021 Mission & Priority document (MPD) – Action

Memorandum Summary

The Quality, Safety & Oversight Group (QSOG) and Survey Operations Group (SOG) remain dedicated to ensuring the health and safety of all Americans. The FY 2021 MPD was updated to reflect this dedication, along with our ongoing commitment to strengthen oversight, enhance enforcement, increase transparency, improve quality and reduce burden.

FY 2021 MPD updates include:

- Joint issuance of the MPD by both QSOG & SOG
- Information regarding ongoing survey and certification priorities during the Coronavirus disease 2019 (COVID-19) public health emergency (PHE)
- Updates based on guidance released in FY 2020
- Based on the re-organization in November 2019, the MPD was updated to reflect the change in designation from CMS Regional Offices to CMS Locations
- Contact information for each of the survey & certification areas

As priorities may change throughout the year, we aim to have the MPD be a living and continuous document which can be updated on a timely basis.

Background

The MPD is an annual document, which directs and outlines the work of QSOG, SOG, and State Survey Agencies (SAs) based on regulatory changes, adjustments in budget allocations, and new initiatives, as well as new requirements based on statutes. The MPD discusses survey, certification and enforcement functions, as well as the Medicare funding allocation process for states, which directly affects prioritization and planning work for the required survey workload in the fiscal year the MPD is issued. Survey activities must be scheduled and conducted in accordance with the priority tier structure provided in the MPD. The four priority tiers reflect statutory mandates and program emphases, with tier 1 being of the highest priority and tier 4 being lower priority.

In addition, the MPD provides background information for each of the 17 provider and supplier types, accreditation/deemed surveys, and CMS priorities for initial surveys of providers and suppliers enrolling in Medicare. It also outlines the priorities for surveying relocations of existing providers and suppliers, projected validation survey workload, system requirements, and state performance standards, and provides the upcoming surveyor training schedule.

This year's MPD was developed with consideration of the ongoing the COVID-19 PHE, including reference to guidance released during the pandemic such as information regarding performance-based funding requirements tied to the CARES Act supplemental grants and COVID-19 testing and reporting guidelines for various provider types. At a macro level, the non-COVID-19 portion of the MPD does not have any major prioritization changes compared to the previous year's issuance.

As priorities may change throughout the year, we aim to have the MPD be a living document, which will be updated as needed. Such updates will be communicated via an Admin Info memo. For ease of notification, updates will be made to the MPD and/or download(s) in red, italicized font and posted on the QSOG Mission & Priority Information website: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/QSOG-Mission-and-Priority-Information .

Survey and Certification (S&C) Medicare Funding Allocation Process

The S&C program may operate under the terms and conditions of a Continuing Resolution, with funding based on the previous FY base budget as noted in Appendix 1, column A, until such time that Congress passes a final appropriation containing S&C funding.

Contact: For questions or concerns, please contact your CMS Location.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/CMS Location training coordinators within 30 days of this memorandum.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

Attachment(s): FY 21 Mission & Priorities Document
Appendix 1: FY21 MPD Projected Allocations
Appendix 2: FY 2021 Validation Surveys

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Quality Assurance for the Medicare & Medicaid Programs

FY 2021 Mission & Priorities Document (MPD)

Survey & Certification Activities

Quality, Safety & Oversight Group (QSOG) and Survey Operations Group (SOG)

Table of Contents

I. Purpose & Overview

The Mission & Priorities Document (MPD) is an annual document, based on regulatory changes, adjustments in budget allocations, and new initiatives, as well as new requirements based on statutes, directs and outlines the work of the QSOG, SOG, and the State Survey Agencies (SAs). The MPD discusses survey and certification functions as well as the Medicare funding allocation process for states, which directly impacts the work prioritization and planning for the required survey workload in the fiscal year the MPD is issued.

II. Regulations

a. Proposed regulations

1. CMS-3326-P: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Personnel, Histocompatibility and Alternative Sanctions for Certificate of Waiver Laboratories
   Description: This updates CLIA personnel requirements, alternative sanctions for Certificates of Waiver, and histocompatibility requirements, which, with minor exception, have not been updated since 1992.

2. CMS-3359-P: Reporting of Crimes Occurring in Federally Funded Long-Term Care Facilities and Enforcement under Section 1150B of the Social Security Act
   Description: This proposed rule would implement Section 1150B of the Social Security Act, which authorizes the Secretary to impose civil monetary penalties for failure to report that a reasonable suspicion of a crime has occurred, such as abuse, in accordance with the Elder Justice Act.

3. CMS-3403-P- Continuing Conditions for Coverage (CfC)/ Conditions of Participation (CoP) Flexibilities for Providers and Suppliers —Omnibus Rule
   Description: This rule proposes to make permanent selected regulatory waivers issued to Medicare participating providers and suppliers during the COVID-19 PHE. It also proposes to make some conforming and clarifying revisions to health and safety regulations.

4. CMS-3356-P: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Fee
   Description: This rule updates fees for determination of program compliance and additional fees for laboratories established under the Clinical Laboratory Improvement Amendments (CLIA) regulations as well as the collection of other fees CLIA is authorized to collect, such as fees for revised certificates, post survey follow-up visits, complaint investigations, and activities related to imposition of sanctions.

b. Final regulations

1. CMS-3368-F: Accrediting Organizations- Changes of Ownership
   Description: This proposed rule would add requirements and a specified process to address changes of ownership as they relate to the sale, transfer, and/or purchase of assets of Accrediting Organizations (AOs) with the Centers for Medicare & Medicaid Services (CMS)-approved accreditation programs. This change is intended to provide CMS with advance notice when an AO considers a change of ownership. This will allow CMS the opportunity to review the AO's capability to perform its tasks after a change of ownership has occurred to ensure the ongoing effectiveness of the approved accreditation program(s) and minimize risk to patient safety.

2. CMS-3380-F: Organ Procurement Organizations
   Description: This final rule revises the Organ Procurement Organization (OPO) Conditions for Coverage (CfCs) to increase donation rates and organ transplantation rates by replacing the current outcome measures with new transparent, reliable, and objective outcome measures and revising the other CfCs related to performance measures and competition to drive OPO performance and reduce the disruption that could occur with the implementation of the new outcome measures.

3. CMS-3347-F: Requirements for Long-Term Care Facilities: Regulatory Provisions to Promote Increased Safety and Infection Prevention and Control
   Description: CMS proposed several revisions to the Requirements for Participation for Long Term Care facilities to reduce regulatory burden while still promoting resident health and safety. Once finalized, the survey process will need to be revised to address the new requirements.

4. CMS-3355-F: Clinical Laboratory Improvement Amendments of 1988 (CLIA) Proficiency Testing Regulations Related to Analytes and Acceptable Performance
   Description: This rule updates proficiency testing (PT) regulations under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) to address current analytes (that is, substances or constituents for which the laboratory conducts testing) and newer technologies. This rule may also make additional technical changes to PT referral regulations to more closely align them with the CLIA statute.

5. CMS-5531-IFC: Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program

   Description: This interim final rule with comment /period (IFC) gives individuals and entities that provide services to Medicare, Medicaid, Basic Health Program, and Exchange beneficiaries needed flexibilities to respond effectively to the serious public health threats posed by the spread of the coronavirus disease 2019 (COVID-19).

6. CMS-3401-IFC: Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory revisions in Response to the COVID-19 Public Health Emergency

   Description: This interim final rule with comment period (IFC) revises regulations to strengthen CMS' ability to enforce compliance with Medicare and Medicaid long-term care (LTC) facility requirements for reporting information related to coronavirus disease 2019 (COVID-19), establishes a new requirement for LTC facilities for COVID-19 testing of facility residents and staff, establishes new requirements in the hospital and critical access hospital (CAH) Conditions of Participation (CoPs) for tracking the incidence and impact of COVID-19 to assist public health officials in detecting outbreaks and saving lives, and establishes requirements for all CLIA laboratories to report COVID-19 test results to the Secretary of Health and Human Services (Secretary)in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the Public Health Emergency (PHE).

III. Coronavirus disease 2019 (COVID-19) specific survey & certification guidelines

As the COVID-19 PHE continues, CMS requests SAs and stakeholders stay up to date with guidance released on the policy and administrative information memo sites[1].

a. Coronavirus Aid, Relief and Economic Security (CARES) Act Funding

As part of CMS' commitment to protect the nation's most vulnerable citizens and aid the facilities that care for them, CMS initiated performance-based funding requirement tied to the CARES Act supplemental grants for State Survey Agencies.

States that have completed 100% of their nursing home focused infection control surveys have been able to request their entire FY 2020-FY 2023 CARES ACT funding allocation (at their discretion) and can also apply for redistributed funding from States that failed to meet performance goals.

For more information, please see QSO-20-31-All[2]

b. Nursing Home Testing requirements for COVID-19

On August 25, 2020, CMS published an interim final rule with comment period (IFC). This rule establishes Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents. Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary. QSO-20-38-NH[3] provides guidance for facilities to meet the testing requirements. In addition, the memo contains a revised COVID-19 Focused Survey Tool for surveyors to assess compliance with the testing requirements. The memo also provides survey process guidance regarding the assessment of compliance with the requirements for facilities to designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program (IPCP) at 42 CFR § 483.80(b).

[1] https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions and https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Administrative-Information-Memos-to-the-States-and-Regions

[2] https://www.cms.gov/files/document/qso-20-31-all.pdf

[3] https://www.cms.gov/files/document/qso-20-38-nh.pdf

In FY 2021, CMS will continue the imposition of a CMP for nursing homes that fail to report requisite COVID-19 related data to the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) per §483.80(g)(1) and (2).

For additional information, please also see QSO-20-37-NH[4]

For questions, please contact: DNH_TriageTeam@cms.hhs.gov

c. Mandatory Hospital reporting requirements for COVID-19

In FY 2021, CMS will continue regulatory requirements for all hospitals and critical access hospital(CAHs) at §482.42(e) and 485.640(d), respectively to report information in accordance with a frequency and in a standardized format as specified by the Secretary during the PHE for COVID-19.

CMS will continue to impose penalties, including termination from the Medicare and Medicaid programs, for failing to report data needed to support broader surveillance of COVID-19.

For additional information, see QSO-21-03[5]

For questions, please contact: QSOG_Hospital@cms.hhs.gov

IV. Priority tier structure for survey & certification activities

Overview

Survey activities must be scheduled and conducted in accordance with the priority tier structure provided in this document. The four priority tiers reflect statutory mandates and program emphases, with tier 1 being of the highest priority and tier 4 being lower priority. Planning for lower-tiered items presumes that the State will accomplish higher-tiered items first.

Of note, it is not necessary to complete tier 1 or tier 2 work before beginning tier 3, if the multi-tier work has been included in the State's submission, approved by CMS, and the higher tier work will be completed by the end of the FY. We also refer States to SC-13-60-ALL[6] for guidance on the scheduling of initial certification surveys for new owners of previously certified providers and suppliers when those new owners have rejected assignment of the seller's Medicare provider agreement or supplier approval. States must not make the scheduling and completion of such surveys a higher priority than their tier 1 and 2 workload, nor of their other initial certification survey workload.

In addition to prioritizing work between tiers 1-4, we suggest States consult with their CMS Location in the prioritization process. States must track their workload quarterly by tier and report the results to the CMS Location 45 days after the close of the quarter. States must also report the full fiscal year 60 days after the close of the fiscal year. As part of their oversight and trouble-shooting responsibilities, CMS Locations will monitor and work with States on the performance of the tiered workload.

We note that timely, successful uploading of completed survey kits in the designated electronic system is an essential component of the States' workload. States must implement measures to assure that these uploads are completed.

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[4] https://www.cms.gov/files/document/qso-20-37-clianh.pdf

[5] https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/interim-final-rule-ifc-cms-3401-ifc-requirements-and-enforcement-process-reporting-covid-19-data

[6] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-60.pdf

In an effort to streamline the enrollment process for Medicare-certified providers/suppliers, certain certification functions performed by the Survey Operations Group will transition to CMS' Center for Program Integrity (CPI) Provider Enrollment Oversight Group (PEOG) and the Medicare Administrative Contractors (MACs). The MACs will process changes on the enrollment application without an approval recommendation from SOG and will coordinate directly with the State, when necessary. CPI/PEOG will be responsible for signing applicable provider agreements on behalf of CMS. The transition of certification enrollment work has commenced with voluntary terminations and the transition of enrollment certification work will continue to occur throughout FY2021. SOG will still remain responsible for processing enforcement actions. For additional information on the transition, please see Admin Info memorandum 20-08-ALL[7].

V. Provider & Supplier Oversight

Note on Statistical Convention used through section V:

Whenever standards are expressed in months, 0.9 of the succeeding month is included in order to permit completion of any survey in progress. Hence a 12-month average is tracked as 12.9 months. Similarly, a 3 year interval is tracked as 36.9 months and a 6 year interval is tracked at 72.9 months.

a. Deeming options

Due to ongoing survey and certification resource constraints, initial certifications of providers/suppliers, with the option to achieve deemed Medicare status through accreditation by an Accrediting Organization (AO) with CMS-approved deeming authority, are a tier 4 priority for SAs.

Despite the option for accreditation, End Stage Renal Dialysis Facilities (ESRD) initial surveys will be a tier 1 priority because of the statutory requirement that initial surveys begin within 90 days after the Medicare Administrative Contractor approves the CMS-855[8].

Providers/Suppliers with an accreditation option include:

- Ambulatory Surgical Centers
- Critical Access Hospitals (CAHs) (including swing bed services)
- Home Health Agencies (HHA)
- Hospices
- Hospitals (including swing bed services)
- Rehabilitation Agencies (OPT and SLP)
- Rural Health Clinics
- Psychiatric Hospitals
- End Stage Renal Disease (ESRD) Facilities

All other newly applying providers/suppliers not listed in tier 3 will be classified as tier 4 priorities, unless approved on an exception basis by the CMS Location due to serious healthcare access considerations or similar special circumstances.

These affected Medicare providers/suppliers include:

- Comprehensive Outpatient Rehabilitation Facilities (CORF)
- Hospital-based Distinct Part Skilled Nursing Facilities
- Nursing Homes that do not participate in Medicaid

[7] https://www.cms.gov/files/document/admin-info-20-08-all-revised.pdf
[8] https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS019480

- Portable X-Ray Suppliers

b. Ambulatory Surgical Centers (ASCs)

Definition of an ASC

Medicare-certified ASCs operate exclusively for the purpose of providing surgical services to patients who do not require hospitalization and expected duration of services does not exceed 24 hours.

Medicare-certified ASCs must comply with Medicare health and safety standards found at 42 CFR Part 416, including the Conditions for Coverage (CfCs). There are approximately 5700 Medicare-certified ASCs in the US.

AOs with CMS-Approved ASC Deemed Status Programs

Currently, there are four AOs:

- Accreditation Association for Ambulatory Health Care, Inc. (AAAHC)
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- Healthcare Facilities Accreditation Program (HFAP)
- The Joint Commission (TJC)

Infection Control Surveyor Worksheet Use and Collection

States must continue to use the Infection Control Surveyor Worksheet for each full survey of an ASC to ensure that all areas listed on the worksheet are assessed.

Because of the ongoing use of the infection control surveyor worksheet as part of the standard survey process as well as a focused effort on burden reduction and ASC stakeholders using the publically available worksheet as a self-assessment tool, CMS will not be selecting a random sample list of ASCs and will not be collecting worksheets in FY2021. As CMS builds and explores the capabilities of iQIES, there may be future opportunities to upload completed worksheets as part of the survey kit for CMS to collect as needed.

Beneficial Surveyor and ASC Facility Online Training Courses

The following courses are available 24/7 online via the CMS Quality, Safety and Education Portal (QSEP) (https://qsep.cms.gov/welcome.aspx) for ASC surveyors as well as Medicare-certified ASCs and may be useful:

- Ambulatory Surgical Center Basic Training
- Ambulatory Surgical Center Refresher Training
- Universal Infection Prevention and Control

ASC Resource Information

ASC Regulations – Conditions for Coverage (CfCs) 42 CFR 416.2 – 54[9]
ASC Interpretive Guidelines State Operations Manual: Appendix L[10]
ASC Infection Control Surveyor Worksheet[11]

[9] http://www.ecfr.gov/cgi-bin/text-idx?SID=e01cd47ee54f1061862f7dc7f41e5647&mc=true&tpl=/ecfrbrowse/Title42/42cfr416_main_02.tpl
[10] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_l_ambulatory.pdf
[11] http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107_exhibit_351.pdf

Priority tier structure for survey & certification activities for ASCs

Tier 1	Tier 2	Tier 3	Tier 4
Representative Sample Validation Surveys - Deemed ASCs: States conduct validation surveys of 5% - 10% of deemed ASCs, assigned by CMS (Budgeted separately via supplemental allocation). **Complaint investigations prioritized as immediate jeopardy – deemed ASCs:** only with CMS Location authorization; survey to be initiated within 2 days of CMS Location authorization.	**Targeted Surveys (25%):** The state performs surveys totaling 25% of all non-deemed ASCs in the State (or at least 1, whichever is greater) focusing on ASCs not surveyed in more than 4 years or based on state judgment for those ASCs more at risk of quality problems. Some of the targeted surveys may qualify to count toward the tier 3 priority. States with only 7 or fewer non-deemed ASCs must survey at least 1 ASC unless all non-deemed ASCs were surveyed within the prior two years. **Complaint investigations prioritized as non- IJ high**: to be initiated within 45 days (for deemed ASCs, within 45 days of CMS Location authorization).	**6-Year Interval:** Additional surveys are done to ensure that no more than 6 years elapse between surveys for any one particular non-deemed ASC.	**Initial Surveys**

Contact Information

For questions, please contact: QSOG_ASC@cms.hhs.gov

c. Providers of Outpatient Physical Therapy and Speech-Language Pathology Services

Overview

Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy (OPT) and Speech-Language Pathology (SLP) Services are required to be in compliance with the Federal requirements set forth in the Medicare Conditions of Participation (CoP) in order to receive Medicare/Medicaid payment. Outpatient rehabilitation therapy services include physical therapy (PT), including aquatic therapy, occupational therapy (OT), and speech-language pathology (SLP) services.

Many rehabilitation agencies provide services from extension sites (an additional approved practice location) or in other off-premises locations in addition to their primary site of certification. SAs should ensure extension locations are incorporated into the survey process by selecting a sample of extension locations to survey in addition to the primary site. Additionally, SAs should inquire about off-premises services to determine if these should be extension locations (see SOM Chapter 2, Section 2300).

In FY2006, CMS began issuing identifiers to rehabilitation agency extension locations to ensure that CMS and SAs were aware of the existence of such locations. It is important for the SAs to verify that the rehabilitation agencies with extension locations are providing oversight (administrative and supervisory) for all their locations.

Since these facilities have a deeming option, surveys of new OPTs are a tier 4 priority. In future years we will, as funding permits, require validation surveys for a representative sample of deemed OPTs.

Priority tier structure for survey & certification activities for Providers of Outpatient PT & Speech-Language Pathology services

Tier 1	Tier 2	Tier 3	Tier 4
Complaint investigations prioritized as immediate jeopardy **OPT Representative Sample Validation Surveys**: Surveys are conducted in a sample of deemed OPT's specified by CMS (Budgeted separately and allocated as supplemental funding during the year).	**5% Targeted Surveys**: Each year, the state surveys 5% of the providers in the state (or at least 1, whichever is greater), based on state judgment for those providers more at risk of quality problems. Some of the targeted surveys may qualify to count toward the tier 3 and 4 priorities. States with fewer than 7 providers of this type are exempt from this requirement. **Complaint investigations prioritized as non-IJ high**: to be initiated within 45 days (for deemed, within 45 days of CMS Location authorization).	**7-Year Interval**: Additional surveys are done to ensure that no more than 7 years elapse between surveys for any one particular provider.	**6-Year Avg:** Add'l surveys are done (beyond tiers 2-3) such that all non-deemed providers in the state are surveyed, on average, every 6 years. (i.e., total surveys divided by total providers is not less than 16.7% = 6 years). There is now a deemed status option for OPTs

Contact Information

For questions, please contact: QSOG_OPT@cms.hhs.gov

d. Comprehensive Outpatient Rehabilitation Facilities (CORFs)

Overview

A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients for the rehabilitation of injured, disabled, or sick persons, at a single fixed location, by or under the supervision of a physician and meets all the requirements of Subpart B – Conditions of Participation: Comprehensive Outpatient Rehabilitation Facilities. There are approximately 164 Medicare certified CORFs in the U.S.

Survey & certification activities for CORFs

Due to budgetary constraints, CORF applicants may be unable to receive initial surveys. Also see: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CORFs.html

Priority tier structure for survey & certification activities for CORFs

Tier 1	Tier 2	Tier 3	Tier 4
Complaint investigations prioritized as immediate jeopardy	**5% Targeted Surveys**: Each year, the state surveys 5% of the providers in the state (or at least one, whichever is greater), based on state judgment for those providers more at risk of quality problems. Some of the targeted surveys may qualify to count toward the tier 3 and 4 priorities. States with fewer than 7 providers of this type are exempt from this requirement.	**7-Year Interval:** Additional surveys are done to ensure that no more than 7 years elapse between surveys for any one particular provider.	**6-Year Avg:** Additional surveys are done (beyond tiers 2-3) such that all non-deemed providers in the state are surveyed, on average, every 6 years. (i.e., total surveys divided by total providers is not less than 16.7% = 6 years).

Contact Information

For questions, please contact: QSOG_CORF@cms.hhs.gov

e. Community Mental Health Centers (CMHCs)

The regulations at 42 CFR Part 485, Subpart J (Conditions of Participation (CoPs): CMHCs) provides health and safety CoPs SAs provide the survey and oversight of CMHCs since October 29, 2014. Final interpretive guidance and survey process was published in Appendix F of the SOM on December 6, 2019. The survey interval for the CMHCs, utilizing these regulations, will be every five (5) years and fall into a tier 3 workload. CMS provides national self-paced training for the survey of the CMHCs.

For additional guidance, please see: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/CommunityHealthCenters.html and https://www.cms.gov/files/document/som107apfcmhc.pdf

Survey & certification activities for CMHCs

CMS enters into agreements with CMHCs pursuant to the provision of Partial Hospitalization Services. CMHCs must provide at least 40% of their services to non-Medicare patients. This requirement is monitored by the Medicare Administrative Contractor (MAC).

Priority tier structure for survey & certification activities for CMHCs

Tier 1	Tier 2	Tier 3	Tier 4
Complaint investigations triaged as IJ	**5% Targeted Surveys**: Each year, the state surveys 5% of the providers in the state (or at least one, whichever is greater), based on CMS Location judgment for those providers more at risk of quality problems. Some of the targeted surveys may qualify to count toward the tier 3 priorities. Targeted sample requirements do not apply to states with fewer than 7 CMHCs.	**5-Year Interval**	**Initial certification of CMHCs unless there is verification of access concerns.**

Contact Information

For questions, please contact: CMHC@cms.hhs.gov

f. Dialysis (ESRD) Facilities

Overview

A dialysis facility provides outpatient maintenance dialysis services, and/or home dialysis training and support services. A dialysis facility may be an independent or hospital-based unit. Dialysis facilities must be certified for inclusion in the Medicare Program by validating that the care and services of each facility meet specified safety and quality standards set forth by the Conditions for Coverage at 42 CFR Part 494.

Accreditation for ESRD Facilities

Effective January 4, 2019, ESRD facilities were given the option to seek entry into the Medicare program through a CMS-approved accrediting organization. Currently, there are two accrediting organizations which have received approval from CMS for accreditation of dialysis facilities that are required to meet the conditions and requirements under 42 CFR Part 494:

- National Dialysis Accreditation Commission (NDAC)
- Accreditation Commission for Health Care (ACHC)

Continued efforts

States are responsible for conducting initial, recertification, complaint and associated revisit surveys of ESRD facilities (whether independent or hospital-based). ESRD suppliers may participate through deemed status for initial and recertification surveys by a CMS-approved accrediting organization.

Notable aspects of the ESRD survey responsibilities include:

- QSOG data website for ESRD data reports: the state is responsible for assigning a Master Account Holder, and reviewing, at least annually, the state-specific data which is available on the CMS ESRD data Web site at www.dialysisdata.org. The ESRD data reports on this site provide information on patient characteristics, treatment patterns, hospitalizations, mortality, and transplantation patterns for each Medicare-certified facility. States are responsible for using these data reports to better understand and monitor the performance of individual dialysis facilities and the performance of the state as a whole relative to ESRD practice patterns and outcome performance.
- SAs and the CMS Locations are expected to use data reports to inform the ESRD survey process. Surveyors must use the data as a key consideration when scheduling recertification surveys (e.g. to ensure expected frequency of surveys), preparing for onsite surveys (e.g., to identify areas of risk or needed focus), and selecting which dialysis facilities to survey for priority (i.e. targeted) surveys. Each state is expected to use the state rank-ordered Outcomes List with frequency rates; the facility-specific Dialysis Facility Reports (DFR); and the facility-specific pre-populated Pre-Survey DFR Extract for these purposes.

Requirements for ESRD Surveyors:

- State Specialization of ESRD surveyors: states are expected to maintain a sufficient number of qualified ESRD surveyors. States must be prepared to survey ESRD facilities for such technically and clinically complex areas as water treatment safety, dialyzer reuse safety, specialized infection control and prevention precautions, equipment operation and maintenance, and assessing clinical outcomes. The emphasis of the ESRD Core Survey process focuses on those practice patterns that are known to affect mortality and to provide potential safety risks to patients.
- Minimum Requirements for Qualified ESRD Surveyor(s): The specialized and complex nature of the equipment and processes required for dialysis and for the safe, effective care and clinical management of an ESRD patient's course of treatment demands an equally complex survey process. The ESRD Core survey process is not intuitive and, to be implemented effectively, requires the surveyor to possess significant knowledge in the technical aspects of water treatment, dialysate preparation, infection control, dialysis equipment usage and maintenance, as well as in the safe care and clinical management of the many complex medical, psychosocial, and economic effects that ESRD has on each patient.

Prior to inclusion on an ESRD survey team (except as an observer or trainee/orientee), the surveyor must complete the following requirements:

- Online basic training, available on-demand on the Quality Safety and Education Portal https://qsep.cms.gov/welcome.aspx
    - ESRD Basic Core Survey Training
    - Immediate Jeopardy (Update) Training
    - Emergency Preparedness Basic Training
- Surveyor Field Experience
    - On-the-job participation in at least two ESRD surveys with preceptor including return demonstration of tasks

- After successful completion of one ESRD survey with a preceptor, the new surveyor must complete one additional supervised ESRD survey as lead surveyor

Survey & certification activities for ESRD

As updated in the State Operations Manual, Chapter 2 for ESRD, requests for relocations, expansion of services, and/or addition of stations no longer automatically require an onsite survey. CMS Locations are to use the information available to them to determine whether an onsite survey or a desk review is most appropriate to process the request. If a CMS Location or SA receives a request for the above actions and determines that an onsite survey is needed, this should be treated as a tier 3 priority and completed as such. See State Operations Manual, Chapter 2, Section 2280 for additional guidance.

States are responsible for monitoring ESRD programs by using the following:

- CMS S&C data web site for ESRD data reports: the state is responsible for assigning a Master Account Holder, and reviewing the State-specific data, which is available on the CMS ESRD data Web site at https://www.dialysisdata.org. States are responsible for using these data reports to inform the survey process. Each State is expected to use the state rank-ordered Outcomes List with frequency rates; the facility-specific Dialysis Facility Reports (DFR); and the facility-specific pre-populated Pre-Survey DFR Extract for these purposes.
- The ESRD Outcomes List: focus of the outcomes list continues to be on the top 5% of ESRD facilities with poor clinical outcomes across four defined clinical measures. These measures were chosen based upon their potential to significantly impact patient outcomes and include:
    - Mortality
    - Hospitalizations
    - Hospitalizations related to septicemia
    - Long-term catheter use

States are expected to survey ***all*** identified facilities on the Outcomes List. The annual process for releasing and reviewing the Outcomes List will remain the same.

The ESRD Core Survey Process has been revised to require that surveyors conduct visits to a minimum of two nursing homes where dialysis patients may be receiving their treatments as home dialysis. This additional task will increase on-site survey time.

Priority tier structure for survey & certification activities for ESRD

Tier 1	Tier 2	Tier 3	Tier 4
Investigation of complaint allegations triaged as IJ **Initial surveys**: States must conduct initial certification surveys within 90 days of the MAC approval of the CMS-855 unless the	**Outcomes List**: 100% of the ESRD facilities in the State on the Outcome List ***Investigations of complaint allegations triaged as Non-IJ High***	**3.5-Year Max Interval (42.9 months)**: Additional surveys are done to ensure that no more than 3.5 years elapses between surveys for any one particular ESRD facility ***Non-IJ medium complaints and***	**3-Year <u>Average</u>:** Additional surveys are done (beyond tiers 2-3) sufficient to ensure that ESRD facilities are surveyed with an average frequency of 3 years or less

supplier has elected a deeming option.		***relocations, expansion of service(s), and/or addition of station(s) requests***	

Contact Information

For questions, please contact: ESRDQuestions@cms.hhs.gov

g. Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

Definition of a Rural Health Clinic (RHC) and a Federally Qualified Health Center (FQHC):

Medicare-certified RHCs are located in a rural areas designated as a shortage area, is not a rehabilitation agency or a facility primarily for the care or treatment of mental diseases. FQHCs are located in both rural/urban areas designated as a shortage area.

RHCs operate for the main purpose of providing primary care services to Medicare patients located in rural and shortage areas; FQHCs provide primary care services and dental care services to rural/urban areas and shortage areas. Both RHCs and FQHCs must comply with the applicable Medicare health and safety standards found at 42 CFR Part 491, including the Conditions for Certification/Coverage (CfCs). There are approximately 4,700 Medicare-certified RHCs and 9870 Medicare-certified FQHCs.

Certification and recertification surveys are not required for FQHCs. However, CMS investigates complaints that make credible allegations of substantial violations of CMS regulatory standards for FQHCs as a tier 2 priority. States will use most of the same health and safety standards as they do for RHCs when investigating FQHC complaints.

Accreditation Organizations with CMS-Approved RHC Deemed Status Programs

Currently there are two:

- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)
- The Compliance Team (TCT)

Beneficial Surveyor and RHC/FQHC Facility Online Training Courses

The following courses are available 24/7 online via QSEP (https://qsep.cms.gov/welcome.aspx) for RHC and FQHC surveyors as well as Medicare participating RHCs and FQHCs and may be useful:

- Rural Health Clinic/Federally Qualified Health Centers Basic Training

RHC/FQHC Resource Information

- RHC/FQHC Regulations – Conditions for Certification/Coverage (CfCs) 42 CFR 491: https://www.ecfr.gov/cgi-bin/text-idx?SID=e29a6f8a9ca044bb56e976a23e775a8d&mc=true&tpl=/ecfrbrowse/Title42/42cfr491_main_02.tpl
- RHC Interpretive Guidelines State Operations Manual: Appendix G https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_g_rhc.pdf

Survey & certification activities for FQHCs and RHCs

States will survey a 5 percent targeted sample of RHCs, with at least one in those states where 5 percent is less than one RHC. States will select the sample, focusing on RHCs that have not been surveyed in

more than six years and/or RHCs that represent a greater risk of quality problems based on their recent compliance history or other factors known to the state. States should use their individual history of growth, in addition to any State and local events/initiatives, as a guide to project workloads. This Tier 2 sample is not required for any State that has fewer than seven RHCs. Since FY2015, RHC initial surveys are a tier 4 priority, as these facilities now have two deeming options. Please see Appendix 2 for FY 2021 validation surveys as specified by CMS. States with less than ten deemed RHCs are exempt from performing validation surveys.

Priority tier structure for survey & certification activities for FQHC and Rural Health Clinics

Tier 1	Tier 2	Tier 3	Tier 4
Complaint investigations prioritized as immediate jeopardy. Deemed RHCs: only with CMS Location authorization; survey to be initiated within 2 days of CMS Location authorization. **Complaint investigations prioritized as immediate jeopardy FQHCs**: only with CMS Location authorization; survey to be initiated within 2 days of CMS Location authorization. **Validation surveys are conducted in a sample of deemed RHCs, specified by CMS.** (Budgeted separately and allocated as supplemental funding during the year.)	**5% Targeted Surveys**: Each year, the State surveys 5% of non-deemed RHCs (or at least 1, whichever is greater), based on State judgment for those RHCs most at risk of quality problems Some of the targeted surveys may qualify to count toward the Tiers 3 and 4 priorities. States with fewer than 7 RHCs of this type are exempt from this requirement. **Complaint investigations prioritized as non- IJ high**: to be initiated within 45 days (for deemed RHCs, or FQHCs within 45 days of CMS Location authorization).	**7-Year Interval:** Additional surveys are done to ensure that no more than 7 years elapse between surveys for any one particular RHC.	**6-Year Avg:** Additional surveys are done (beyond tiers 2-3) such that all non-deemed RHCs in the State are surveyed, on average, every 6 years. (i.e., total surveys divided by total RHCs is not less than 16.7% =6 years). **Initial Survey- there is a deemed status option for RHCs.** There is no certification or recertification for FQHCs.

Contact Information

For questions, please contact: QSOG_RHC-FQHC@cms.hhs.gov

h. Home Health Agencies (HHAs)

Non-Deemed Home Health Agencies (HHAs)

- Basic Expectations: Under Section 1891(b) of the Act, the Secretary is responsible for assuring that CoPs and the resulting enforcement are adequate to protect the health and safety of individuals under the care of an HHA and to promote the effective and efficient use of Medicare funds. In accordance with Sections 1861(o), 1864 and 1891(c) of the Act, SAs conduct surveys of HHAs to determine whether they are complying with the CoPs.

HHAs must be surveyed via a standard survey at least every 36.9 months. This is not an average of 36.9 months; it is a maximum interval between surveys for any one particular HHA. The Medicare statute established the 36-month interval commensurate with the need to assure the delivery of quality home health services. Comprehensive State performance standards for compliance with the 36.9-month statutory requirement continue to apply.

- Activation, De-activation, and Change of Ownership (CHOWs): Since January 1, 2010, a provider or supplier who does not submit any Medicare claims for 12 consecutive calendar months is subject to having its Medicare billing privileges deactivated. This may occur when an HHA is primarily providing services to Medicaid or other third party payer sources that require Medicare certification. Deactivated agencies and suppliers with a payment suspension remain certified and must continue to be surveyed at least every 36.9 months. When a provider seeks to reactivate billing privileges, a standard survey is conducted as a recertification survey with a note that this is an early recertification due to a request for reactivation of Medicare billing.

  In addition to the requirements outlined under 42 CFR §489.18, if an HHA undergoes a CHOW within 36 months of the effective date of the provider's enrollment into Medicare, or subsequent asset sale, stock transfer or CHOW, the provider agreement and Medicare billing privileges do not convey to the new owner. An initial survey will be required. The initial surveys will be considered tier 4 of the survey priorities, and the HHA may utilize an approved AO for a deeming survey and follow existing procedures. It is the responsibility of the HHA to arrange the Medicare survey with the AO.

- Surveyor Qualifications: Before any state or federal surveyor may serve on a survey team (except as a trainee) for an HHA survey, he/she must complete the HHA Basic Surveyor Training course located in QSEP.

Deemed Home Health Agencies

States will continue to be responsible for conducting two types of validation surveys for deemed HHAs: substantial allegation complaint surveys and representative sample validation surveys.

Each SA should budget for one representative sample validation survey of its deemed HHAs from its standard allocation, unless it does not have any deemed HHAs located in its State.

Depending on the AOs' actual survey schedules, there may be States with deemed HHAs for which no representative sample validation survey can be assigned within the FY. Each month a sample of scheduled AO surveys is selected for validation. We will inform the SAs promptly if they have been assigned a validation survey. Some States with larger numbers of deemed HHAs have been designated to perform more of these representative sample validation surveys once they have completed the one survey provided for in the standard allocation. For these States, a supplemental budget allocation will be made for surveys completed beyond the first representative sample validation survey.

Survey Protocol Revision: A new survey protocol is expected to published for HHAs in Appendix B of the SOM in 2021 with a corresponding change to the HHA Basic Surveyor training.

Survey & certification activities for HHAs

CMS is targeting the release of a new survey process for HHAs in FY 2021 and will simplify procedures for moving from standard to partially extended to extended surveys. Home health surveys should include a sample of extension locations.

Additionally:

- QSOG will continue to fund OASIS Education Coordinators (OEC) and OASIS Automation Coordinators (OAC). The OECs will provide technical assistance to the HHA providers in the administration of the OASIS data set. The Division of Chronic and Post-Acute Care (DCPAC) has assumed responsibility for the technical support to OECs.
- The OACs will provide technical assistance to the HHA providers on the transmission of OASIS data. The Division of Quality Systems for Assessments and Surveys (DQSAS) continues to provide technical support to the OACs.

Priority tier structure for survey & certification activities for HHAs

Tier 1	Tier 2	Tier 3	Tier 4
36.9-Mo. Max. Interval: No more than 36.9 month elapses between completed surveys for any particular agency. **Complaint investigations triaged as IJ** **Validation Surveys**: States annually survey a representative sample of deemed HHAs specified by CMS during the year. At least 1 deemed HHA is surveyed, unless the State has no deemed HHAs, or unless CMS makes no assignment. An extended survey is required for any validation survey, which finds one or more condition-level deficiencies. (Each State surveys 1 HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) **Substantial Allegation Validation (Complaint)**	Substantial Allegation (Complaint) Investigations	N/A	**24.9 Mo. Avg**: Additional surveys (beyond tiers 1-3) done based on state judgment regarding HHAs most at risk of providing poor care so all HHAs are surveyed on avg. every 24 mos. (average of all tier 4 surveys ≤ 24.9 mos. in order to optimize unpredictability of surveys. Surveys of HHAs de-activated (by the MAC) –for failure to bill Medicare for 12 consecutive months. Initial surveys of HHA's following a CHOW where the provider agreement and billing privileges do not convey to the new owner.

Surveys - IJs: Only when authorized by the CMS Locations, complaint surveys are to be initiated and completed within the applicable SOM timeframe and are tier 1 priority.			

Contact Information

For questions, please contact: HHAsurveyprotocols@cms.hhs.gov

i. Hospice Agencies

Overview

Under the IMPACT Act of 2014, each Medicare certified hospice must be surveyed by the SAs or AOs no less frequently than every 36 months. Funding provided through the IMPACT Act as well as the QSOG S&C Medicare program management budget will assist states in meeting this requirement.

The IMPACT Act funds must be separately accounted. States should use their IMPACT funds first, and then use the Medicare S&C funds for expenses that exceed their IMPACT fund allocation. States may also request additional IMPACT funds if they are clearly exceeding their IMPACT allocation by contacting their CMS Location budget contact.

The SA is expected to have a system in place for nursing home surveyors to report to the SA those nursing facilities, which are providing hospice services to residents and any concerns they have about the provision of hospice services in a specific facility. SAs are expected to follow-up and initiate enforcement action against a hospice when they identify hospice non-compliance issues associated with care to nursing home residents who have elected the hospice benefit.

Before any state or federal surveyor may serve on a survey team (except as a trainee) for a hospice survey, he/she must complete the Basic Hospice training course.

Deemed Hospice Agencies

In FY 21, states will continue to be responsible for conducting two types of validation surveys for deemed Hospices: substantial allegation complaint surveys and representative sample validation surveys.

Each SA should budget for one representative sample validation survey of its deemed Hospices from its standard allocation, unless it does not have any deemed Hospices located in its State.

Depending on the AOs' actual survey schedules, there may be States with deemed Hospices for which no representative sample validation survey can be assigned within the FY. Each month a sample of scheduled AO surveys is selected for validation. We will inform the SAs promptly if they have been assigned a validation survey. Some States with larger numbers of deemed Hospices have been designated to perform more of these representative sample validation surveys once they have completed the one survey provided for in the standard allocation. For these States, a supplemental budget allocation will be made for surveys completed beyond the first representative sample validation survey.

Survey & certification activities for Hospice agencies

Hospice surveys should include a sample of multiple locations in the survey process. This sample should be included minimally in the record reviews and onsite visits when possible.

CMS is working on revisions to the hospice survey process with a target release date of late 2021.

Priority tier structure for survey & certification activities for Hospice agencies

Tier 1	Tier 2	Tier 3	Tier 4
36-Month Max. Interval: No more than 36 months between completed surveys for any particular agency. Use the separately-tracked IMPACT hospice funds first. **Representative Sample validation surveys of deemed hospices**: States conduct validation surveys of deemed hospices, specified by CMS (Budgeted separately via supplemental allocation). **Complaint investigations prioritized as immediate jeopardy – deemed hospices**: only with RO authorization; survey to be initiated within 2 days of CMS Location authorization.	**Complaint investigations: High**	N/A	**Initial Surveys**

Contact Information

For questions, please contact: QSOG_Hospice@cms.hhs.gov

j. Hospitals and Psychiatric Hospitals

The below information highlights both hospital and psychiatric hospitals.

Hospitals

Swing-bed requirements will continue to be surveyed as part of a scheduled hospital or CAH survey, and do not need to be targeted for a separate, stand-alone survey, unless:

- There is a swing-bed requirement complaint in a hospital or CAH;
- A non-deemed hospital or CAH is applying for an initial swing-bed approval, in which case, the survey is conducted by the SA; or
- A deemed hospital or CAH is applying for an initial swing bed approval, in which case, the survey is conducted by the AO.

Note - For non-deemed hospitals or CAHs that wish to add swing-beds as a new service, see the tier status for scheduling those surveys. States must include swing-bed recertification during hospital and CAH recertification surveys.

Appendix A (Hospital guidance) and Appendix W (CAH guidance) swing-bed sections have been updated to align with the LTC rules and refer to Appendix PP (LTC guidance). The guidance for Swing-Beds found in Appendix T has been retired. Appendix A and Appendix W will be utilized for surveying hospitals and CAHs, respectively, that have swing-beds. See QSO Memo 18-26-Hospitals,CAHs[12] for additional details.

Emergency Medical Treatment & Labor Act (EMTALA) Investigations

The timeline for investigations in hospitals and critical access hospitals (CAH) for complaints specific to EMTALA and deaths associated with restraint or seclusion has been changed from completion in five working days to initiation within two business days. This change brings these two categories of complaint investigations in line with other potential immediate jeopardy (IJ) investigations in Medicare-participating non-long term care facilities.

For EMTALA complaints, the CMS Location is currently able to triage the complaint investigation as IJ but may now triage the complaint as Non-IJ High, based on their review of the allegations. The Non-IJ High prioritization will require the survey to be initiated within 45 days.

The changes to SOM Chapter 5 and Appendix V will align complaint investigative timelines in non-long term care facilities for IJ prioritization. See QSO Memo 19-14-Hospitals,CAHs[13] for additional details.

Psychiatric Hospitals

The majority of Medicare-certified psychiatric hospitals participate via deemed status, based on their accreditation by The Joint Commission (TJC) or DNV GL Healthcare (DNV-GL). However, a small number of psychiatric hospitals have grandfathered partially deemed status, i.e., they are deemed for the regular hospital CoPs only by the Accreditation Association for Hospitals/Health Systems Healthcare Facilities Accreditation Program (AAHHS/HFAP) or DNV GL, leaving states responsible for surveying them for the two special conditions. This practice stems from a time when no AO had an approved psychiatric hospital Medicare deeming program. Although CMS no longer permits AAHHS/HFAP or DNV GL to partially deem new psychiatric hospital clients, we have grandfathered their existing psychiatric hospital clients. There are less than ten hospitals that remain partially deemed and partially under state jurisdiction. In addition, roughly 11% of all psychiatric hospitals are completely non-deemed. TJC and DNV-GL are currently the only approved accreditation organizations for psychiatric hospitals. Please continue to check the CMS website for a current listing https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Accreditation-of-Medicare-Certified-Providers-and-Suppliers

CMS previously maintained a contracted cadre of psychiatric consultant surveyors to conduct surveys of the two special conditions. However, this contract ended on March 31, 2020, and the SAs assumed full responsibility for conducting these surveys. The states now conduct the psychiatric surveys for the two special conditions at the same time they conduct surveys for the regular hospital conditions in psychiatric hospitals.

[12] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO18-26-Hospital-CAH.pdf

[13] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-14-Hospitals-CAHs.pdf

Priority tier structure for survey & certification activities for Hospitals, Psychiatric Hospitals, & CAHs (Deemed)
Priority tier structure for survey & certification activities for Hospitals, Psychiatric Hospitals, & CAHs (Non-Deemed)

Contact Information

For questions, please contact: QSOG_Hospital@cms.hhs.gov

k. Critical Access Hospitals (CAHs)

Overview

CAHs are required to be in compliance with the federal requirements set forth in the Medicare CoPs in order to receive Medicare/ Medicaid payment. The goal of a CAH survey is to determine if the CAH is in compliance with the CoP set forth at 42 CFR Part 485 Subpart F.

- The most current CAH interpretive guidance, the State Operations Manual (SOM) Appendix W, can be found at – https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_w_cah.pdf

Certification of CAH compliance with the CoPs is accomplished through observations, interviews, and document/record reviews. The survey process focuses on a CAH's performance of organizational and patient-focused functions and processes. The CAH survey is the means used to assess compliance with federal health, safety, and quality standards that will assure that the beneficiary receives safe, quality care and services.

- See *SOM Chapter 2 - The Certification Process* for additional information - https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107c02.pdf

In order to initially become certified as a CAH, a conversion survey is required. Prospective CAHs must first be certified and enrolled as a hospital, and only thereafter, may seek conversion to CAH status.

- Requests from a non-deemed hospital to be certified as a CAH are, therefore, not treated as initial surveys but as conversions, and may be surveyed as a tier 2, 3, or 4, priority at State option.
- AOs with a CMS-approved CAH program are able to conduct a CAH conversion survey.

For annual CAH recertification, the CMS Location must request from each SA a list of all CAHs expected to undergo a recertification survey over the next 12 months. This list should include and identify both deemed and non-deemed CAHs. For CAHs that are deemed, the SA reviews the deemed status tab in the Automated Survey Processing Environment (ASPEN) for accreditation dates of CAHs. Prior to the date of a SA or AO CAH recertification survey, the CMS Location must determine whether the CAH meets the rural location and distance requirements.

- Information regarding the *CAH Recertification Checklist: Rural and Distance or Necessary Provider Verification* within the S&C Memo-16-08-CAH (REVISED 09.02.16) can be found at -

https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-16-08.pdf

For CAHs adding a provider-based location, a CAH submits a provider-enrollment application (Form CMS-855) to its affiliated MAC noting that it is adding a provider-based location. The CAH should also submit documentation noting how it continues to comply with the CAH distance requirements at 42 CFR 485.610(e)(2) to ensure that the CAH will retain its status as a CAH.

The MAC reviews the CAH's Form CMS-855 for the addition of a provider-based location and, once completed, forwards the form and any submitted documentation to their CMS Location Division of Survey and Certification (DSC) for review of compliance with 42 CFR 485.610(e)(2). If the CAH does not submit documentation noting how it continues to comply with the CAH distance requirements in the provider-enrollment application (Form CMS-855), the CMS Location DSC requests that information from the CAH during their distance review.

The CMS Location DSC reviews the Form CMS-855 and any corresponding documentation from the CAH, as well as any information received from the SA, for evidence that the CAH's off-campus provider-based location is more than a 35 mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from another hospital or CAH.

If the CMS Location DSC verifies that the CAH will continue to meet the CAH distance requirements with the added provider-based location, the CMS Location DSC issues a tie-in notice and notifies the MAC, the CMS Location Division of Financial Management and Fee for Service Operations (DFMFFSO), and the SA of the tie-in.

However, if the CMS Location DSC review verifies that the CAH's provider-based location does not meet the CAH distance requirements at §485.610(e)(2), the CMS Location DSC notifies the CMS Central Office (CO) for further review before rendering a final determination. Upon reaching a final determination, the CMS Location DSC notifies CO, the MAC, the CMS Location DFMFFSO, and the SA. Once notified of the CMS Location DSC review:

- The MAC does not take further action on the submitted CAH Form CMS-855 to add the provider-based location (under Chapter 15 of the Medicare Program Integrity Manual) until the MAC is notified of the CAH's decision as outlined below.
- The CMS Location DSC informs the CAH that its provider-based location causes the CAH to no longer meet the 42 CFR 485.610(e)(2) distance requirement and offers the CAH the following options (A, B, or C):
    A. **Termination of participation:** By adding the provider-based location, the CAH would be placed on a 90 day involuntary termination track (as outlined in Section 3012 of the SOM) or the CAH can voluntarily terminate its participation from the program all together.
    B. **Continued CAH certification:** The CAH may retain its CAH status by terminating the off-campus provider-based location arrangement that led to the non-compliance with the 42 CFR 485.610(e)(2) distance requirements within the 90 day termination period or by physically moving the provider-based location so that the distance requirements are met.
    C. **Conversion:** The CAH may continue to participate in Medicare by converting to a hospital. If the CAH chooses to convert to a hospital, the CAH would need to submit to the MAC another Form CMS-855 to terminate their CAH enrollment along with a separate Form CMS-855 to enroll as a hospital. The effective date of the CAH's hospital

certification would coincide with the effective date of termination of CAH status. See Section 2005 of the SOM for the Medicare enrollment process.

Once the CMS Location DSC notifies the MAC of its review that the CAH is in compliance with 42 CFR 485.610(e)(2) distance requirements or, if not in compliance, of the CAH's choice of option A, B, or C (as described above), the MAC then proceeds with sending the Form CMS-855 and its recommendation for approval on the provider-based location to its affiliated CMS DFMFFSO for a determination under 42 CFR 413.65.

- The CMS Location DFMFFSO reviews the Form CMS-855 and confers with CMS CO and Location DSC on specific issues as needed.
- The CMS Location DFMFFSO sends the CAH/Hospital (Form CMS-855 applicant) a notice letter with the determination on its request for provider-based location designation, with copies sent to the MAC, CMS Location DSC, and the SA.
- The CMS Location DSC notifies the AOs (for those accredited CAHs deemed as meeting Medicare and Medicaid certification requirements).

Please see updates to Publication 100-07 - SOM Chapter 2

The CMS Center for Program Integrity (CPI), Provider Enrollment Division Publication 100-08 Program Integrity Manual, Chapter 15.10.2(E) instructs the MACs and aligns with the SOM Chapter 2[14] guidance.

Survey & certification activities for CAHs

A conversion survey is required for each new CAH. Prospective CAHs must first be certified and enrolled as a hospital, and then may seek conversion to CAH status. Requests from a non-deemed hospital to be certified as a CAH are, therefore, not treated as initial surveys but as conversions, and may be surveyed as a tier 2, 3, or 4 priorities, at State discretion. Similarly, conversion back from CAH status to non-deemed acute care hospital status is treated as a conversion rather than an initial survey. Generally, CAH's are permitted 12 months to convert back to a non-deemed acute care hospital. CMS expects the states to treat as a tier 2 or 3priority.

- AOs with a CMS-approved CAH program are able to conduct a CAH conversion survey. There are three AOs with approved CAH accreditation programs: AAHHS/HFAP, DNV GL, and TJC.
- In order to routinely re-evaluate the compliance of currently certified CAHs with the status and location requirements at 42 CFR 485.610, CMS developed a CAH Recertification Checklist: Rural and Distance or Necessary Provider Verification for use by CMS Locations staff when processing CAH re-certifications. See S&C: 16-08-CAH (REVISED 09.02.16) for additional details and a copy of the checklist.
- CMS recently clarified the process in the State Operations Manual for adding a provider-based location. See QSO Memo 19-16-CAH[15].
- Swing-bed services will be covered under the Hospitals section. See QSO Memo 18- 26-Hospitals, CAHs[16] for additional swing bed guidance.

[14] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c15.pdf
[15] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO-19-16-CAH.pdf
[16] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions-Items/QSO18-26-Hospital-CAH

Priority tier structure for survey & certification activities for Hospitals, Psychiatric Hospitals, & CAHs (Deemed)

Tier 1	Tier 2	Tier 3	Tier 4
Representative Sample Hospital Validation Surveys: All States perform at least 1 survey and selected States perform additional surveys of the States' deemed hospitals, designed to validate the surveys of AOs with CMS identifying the hospitals to be surveyed by each State. (Entirely funded via the State's regular budget) (See Appendix 2) **Targeted Second (Add'l) Representative Sample Validation Surveys**: Some States conduct add'l surveys from a second sample of deemed hospitals identified by CMS (Second sample % budgeted separately and allocated as supplemental funding during the year). (See Appendix 2) **5% CAH Representative Sample Validation Surveys**: States annually survey a representative sample of deemed CAHs specified by CMS during the year (of the total deemed CAHs, 5% of those deemed CAHs have a validation survey conducted by accrediting orgs, or at least 1 survey	**Substantial Allegation Validation (Complaint) Investigations that are prioritized as non-IJ high must be initiated within 45 days of CMS Location authorization**	N/A	**N/A**

in each state - whichever is greater). At least 1 deemed CAH is surveyed in each State, unless the State has no deemed CAHs, or unless CMS makes no assignment. (Entirely funded out of each State's regular budget) (See Appendix 1) **Substantial Allegation Validation (Complaint) Surveys**: Only when authorized by the CMS Location. IJ complaints, including restraint/seclusion death incidents are to be initiated or completed within the applicable SOM timeframe and are tier 1 priority. **EMTALA Complaint Surveys**: Only when authorized by the CMS Location. All EMTALA complaints surveys authorized are prioritized as IJs or non-IJ high and are to be completed within the applicable SOM timeframe and are a tier 1 priority. **Full Surveys Pursuant to Complaints:** Full surveys may be required by the CMS Location after each complaint investigation that finds condition level non-compliance for deemed hospitals and CAHs. These are a tier 1 priority. **Psychiatric Hospital Representative Sample**			

Validation Surveys: Surveys are conducted in a sample of deemed psychiatric hospitals, specified by CMS. If States are not equipped to evaluate compliance with the special conditions, CMS' contractor will perform that component of the validation survey. (Budgeted separately and allocated as supplemental funding during the year.)			

Priority tier structure for survey & certification activities for Hospitals, Psychiatric Hospitals-& CAHs (Non-Deemed)

Tier 1	Tier 2	Tier 3	Tier 4
Complaint surveys: Complaint allegations prioritized as IJs and CMS Location authorized EMTALA and restraint/seclusion death incident surveys, initiated or completed within the applicable SOM timeframes.	**5-Year Max. Interval**: No more than 5 years elapses between surveys for any particular non-deemed hospital, psychiatric hospital or CAH. **5% Targeted Sample**: States survey at least 1, but not less than 5% of the non-deemed hospitals, 5% of the non-deemed psychiatric hospitals and 5% of non-deemed CAHs in the State, selected by the State based on State judgment regarding those most at risk of providing poor care. Some targeted surveys may qualify to count toward the tier 3 and 4 priorities. Targeted sample requirements do not apply to States with fewer than 7 non- deemed hospitals, psychiatric hospitals or CAHs.	**Recerts: 4-Year Max. Interval:** No more than 4 years elapses between surveys for any particular non-deemed hospital or CAH. **Recerts of Psych Hospitals**: 3 year average recertification surveys of non- accredited/non deemed psychiatric hospitals only. **New IPPS Exclusions:** All new rehabilitation hospitals/ units & new psychiatric units seeking exclusion from IPPS (2), as well as existing providers newly seeking such exclusion. The SA does not need to conduct an on-site survey for verification of the exclusion requirements but instead may process an attestation	**3.0-Year Avg**.: Additional surveys are done (beyond tiers 2 and 3), based on state judgment regarding the non-deemed hospitals and CAHs that are most at risk of providing poor care, such that all non-deemed hospitals/CAHs in the state are surveyed, on avg, every 3 years (i.e., total surveys divided by total non-deemed hospitals/CAHs is not more than 3 years; separate calculation for hospitals and CAHs). Targeted surveys may count toward the 3 yr avg.

Contact Information

For questions, please contact: QSOG_Hospital@cms.hhs.gov

l. Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)

Ongoing Efforts

States have a regulatory obligation to conduct annual surveys of ICFs/IID. These facilities must be surveyed, on average, every 12.9 months with a maximum 15.9 month survey interval. Please see S&C: 12-29-ALL[17]. The comprehensive State performance standards monitor to what extent States are recertifying ICFs/IID on a timely basis.

The President's budget requests Federal funds for the Medicaid portion of LTC survey & certification activities, including recertification surveys and related revisits of ICFs/IID once per year. States are reminded to secure the necessary Medicaid State share for funding those LTC survey and certification activities attributable to Medicaid facilities and dually-certified facilities.

Before any state or federal surveyor may serve on a survey team (except as a trainee) for an ICF/IID survey, he/she must attend the Basic online ICF/IID surveyor training course available on-demand on QSEP.

CMS implemented a focused survey process in FY 2018. The revised process is designed to reduce surveyor time in paperwork review and increase surveyor observations and interactions with the residents and staff.

Also see https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/ICFIID.html

Priority tier structure for survey & certification activities for ICF/IID

Tier 1	Tier 2	Tier 3	Tier 4
15.9 Mo. Max. Interval: No more than 15.9 months elapses between completed surveys for any particular ICF/IID. **12.9-Mo. Avg**: All ICF/IIDs in the State are surveyed, on average, once per year. The Statewide average interval between consecutive standard surveys must be 12.9 months or less. **Complaint surveys triaged as IJ.**	Complaint investigations triaged as Non-IJ	N/A	**Initial Surveys**

[17] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-12-29.pdf

Contact Information

For questions, please contact: QSOG_ICFIID@cms.hhs.gov

m. Long Term Care (LTC)

Continued Efforts over the Past Years

- **Statutory Timeframes:** All skilled nursing facilities (SNFs) and nursing facilities (NFs) are subject to a standard survey that is completed no later than 15.9 months after the previous standard survey, with a statewide average between standard surveys of 12.9 months.
- **Off-hours Surveys**: States must continue to conduct 10 percent of nursing home inspections off-hours (to be started mornings, evenings and/or weekends). These surveys must be completed on consecutive calendar days. Additionally, 50 percent of these surveys (or 5 percent of all surveys) must be conducted on weekends in facilities with potential staffing issues[18].
- **Resident Assessment Instrument/Minimum Data Set (RAI/MDS)**: All certified nursing homes and swing bed hospitals are required to encode and transmit MDS records to CMS in accordance with CMS established specifications and time frames. CMS expects the states to continue to provide staff to serve as RAI/MDS educational and technical resources to nursing homes and SA staff. As such, states must continue to adequately fund and staff the positions of a RAI coordinator and a RAI/MDS automation coordinator. The State RAI coordinator and the RAI/MDS automation coordinators will be responsible for:
    - Maintaining an up-to-date working knowledge of the RAI manual and MDS 3.0 assessment;
    - Attending all mandatory training sessions and demonstrating competency and skills in the RAI process, including coding and transmitting the MDS 3.0;
    - Participating in CMS-sponsored workgroups, meetings, and conferences;
    - Conducting at least two structured provider training courses within the fiscal year, and provide ongoing RAI/MDS education and technical support to SNF/NF and swing bed hospital providers, and SA staff (training courses shall be documented and reportable to CMS); and
    - Educating providers and SA staff on reports from the data system, MDS outcome or other reports
- **State Medicaid funding**: States must secure the necessary Medicaid State share for funding those activities attributable to Medicaid facilities or dually-certified facilities.
- **Maintenance of Nurse Aide Training Registry**: States are required to maintain a registry of all individuals who have completed a nurse aide training course and have passed a competency evaluation test. States must also investigate allegations of resident neglect and abuse (including misappropriation of personal funds) by a nurse aide or other individuals. See 42 CFR Subpart D, and Section 4132 and 4141 of the State Operations Manual for additional requirements.
- **Review of Requests for Waiver of Nurse Aide Training Program 2-year Prohibition:** States are required to maintain a list of approved nurse aide training programs. If a program is disapproved due to survey findings, the state has specific authority under the statute to review requests for waiving the disapproval particularly for those facilities where access to other approved programs is an issue. Please see S&C-18-02-NH[19] memo for additional clarification.

[18] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/QSO19-02-NH.pdf
[19] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-18-02.pdf

On-Going Efforts

Enforcement and Civil Money Penalty Tool: CMS will be continuing work on enforcement policies to support compliance. States are required to transfer all cases that warrant enforcement to the CMS Location.

Emergency Preparedness Surveys: Please refer to the Emergency Preparedness website for additional information for these requirements and surveys which began on November 15, 2017. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/Emergency-Prep-Rule.html

State Reinvestment of Civil Money Penalty (CMP) funds (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment): States are required to reinvest CMP funds to improve and protect the health and safety of nursing home residents. CMS has provided additional guidance via Admin Info memo (Admin-18-16-NH[20]). Each annual plan must be submitted by October 31st. They are also required to maintain a plan of how the funds are intended to be reinvested, and report certain metrics about projects funded. CMS will continue to work with States to monitor and ensure the appropriate use of CMP funds.

Standard Health Survey Process

- All states have converted to the new long-term care survey process (LTCSP) to assess compliance with the Requirements for Participation. CMS will continue to make software and guidance updates to existing and new regulations. We will update the LTCSP Procedures Guide and Training documents accordingly.
- Resources for all of these changes can be found on the Quality, Safety & Education Portal (QSEP) at https://qsep.cms.gov/ and at: https://www.cms.gov/Medicare/Provider-Enrollment-and- Certification/GuidanceforLawsAndRegulations/Nursing-Homes.html.
- **Appendix P**: In FY2018, CMS removed Appendix P and incorporated key policy components into Chapter 7 of the State Operations Manual. The Long-Term Care Survey Procedure Guide (https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/LTCSP-Procedure-Guide.pdf) will be the reference guide for the survey process and will be available on our website and in the software program.

Other Areas of Importance

- **National Partnership to Improve Dementia Care**: CMS has established a public goal of reducing the antipsychotic rate by 15% among those facilities that continue to have high rates of antipsychotic usage (i.e., late adopters) by the end of CY 2019. CMS will continue to focus on are reducing the use of antipsychotics in all nursing homes and late adopters throughout. We will communicate any new initiatives, such as new goals or certain foci of the partnership as we progress.
- **Focused Dementia Care Surveys**: In FY2021, CMS plans to have federal contract surveyors conduct additional focused dementia care surveys in some states. Due to concerns about facilities using an inappropriate process to diagnose residents with schizophrenia, we also expect to conduct a limited number of surveys focused on this issue. We welcome States that may want surveyors to observe either of these surveys.

[20] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Administrative-Information-Memos-to-the-States-and-Regions-Items/Admin-Info-Letter-18-16.html

- **Preventing discharges that violate federal requirements (also known as "involuntary discharges"):** CMS remains concerned when residents are discharged in a manner that violates federal requirements and places residents health and safety at risk. CMS requires States to transfer any case that involves noncompliance related to involuntary discharge to their CMS location. CMS locations will evaluate the noncompliance and impose the appropriate enforcement remedy.
- **Facility Reported Incidents and Complaint Investigations**: States should prepare for the release of guidance in Chapter 5 of the State Operations Manual related to the management of facility reported incidents and complaints. This would include the development and implementation of policies and procedures that are consistent with Federal guidelines, adherence to federal timeframes for investigation, the collection of mandated elements from the initial and investigation reports, and the collection of data to support the tracking of facility reported incidents.
  CMS Locations will be working with their states to develop a plan for this work.

Priority tier structure for survey & certification activities for LTC

Tier 1	Tier 2	Tier 3	Tier 4
15.9-Mo. Max. Interval: No more than 15.9 months elapses between completed surveys for any particular nursing home. **12.9-Mo. Avg:** All nursing homes in the State are surveyed, on average, once per year. The Statewide average interval between consecutive standard surveys must be 12.9 months or less. **Complaint investigations triaged as IJ**	**"Off-Hours" Surveys:** States are required to conduct at least 10 percent of the standard health surveys on the weekend or before 8:00 a.m. or after 6:00p.m. (i.e., "off-hours). States shall conduct at least 50% of their required off-hours surveys on weekends using the list of facilities with potential staffing issues provided by CMS. **Complaint investigations triaged as Non-IJ High**	**Initial Surveys of Nursing Homes that are seeking Medicaid-only** – funded only by Medicaid (not Medicare) and surveyed at state priority **Initial Surveys of Nursing Homes seeking dual Medicare/Medicaid certification*** **Complaint investigations triaged as Non-IJ Medium**	**Complaint investigations triaged as Non-IJ Low**

***Note: Conversion of a Medicaid-only Nursing Facility (NF) to dual-certification (SNF/NF)** does not require an initial Medicare certification survey provided all of the following are met: (a) the Medicaid survey has been completed within the prior six months, (b) the majority of beds in the facility will remain Medicaid-certified and (c) the procedures in SOM 7002 are followed for SNFs.*

Contact Information

For questions, please contact: DNH_TriageTeam@cms.hhs.gov

n. Portable X-Ray (PXR) Suppliers

CMS plans to release new interpretive guidance for PXR in FY2021

Priority tier structure for survey & certification activities for PXR

Tier 1	Tier 2	Tier 3	Tier 4
Complaint investigations triaged as IJ	**5% Targeted Surveys:** Each year, the state surveys 5% of the providers in the State (or at least 1, whichever is greater), based on State judgment for those providers more at risk of quality problems. Some of the targeted surveys may qualify to count toward the tier 3 and 4 priorities. States with fewer than 7 providers of this type are exempt from this requirement.	**7-Year Interval**: Additional surveys are done to ensure that no more than 7 years elapse between surveys for any one particular provider.	**Initial Certification Surveys** **6-Year Avg:** Additional surveys are done (beyond tiers 2-3) such that all non-deemed providers in the state are surveyed, on average, every 6 years

Contact Information

For questions, please contact: CMSQSOG_PXR@cms.hhs.gov

o. Psychiatric Residential Treatment Facilities (PRTFs)

The regulation defines a PRTF as "a facility other than a hospital, that provides psychiatric services as described in 42 CFR, Section 441, subpart D, to individuals under age 21, in an inpatient setting." The rule also establishes one Condition of Participation (CoP) for the use of restraint and seclusion that PRTFs must meet in order to continue to provide Medicaid inpatient psychiatric services to patients under 21.

The PRTF general requirements and the CoP specify requirements for treatment team and person-centered active treatment plan; and requirements to protect the residents against the improper use of restraint or seclusion that include, but are not limited to: parental/guardian notification when a restraint or seclusion is used; reporting of deaths and serious occurrences; requirements for licensed practitioner's order for the use of restraint or seclusion; requirements for staff education and training on the use of emergency safety intervention; and requirements for monitoring a resident during and immediately after the use of restraint or seclusion.

The CoP requires that restraint or seclusion be used only during emergency safety situations (ESI), and requires each facility that provides services to individuals under 21 under a Medicaid provider agreement, through an attestation in writing to the State Medicaid Agency at initial certification, that the facility is in compliance with the requirements set forth in the rule.

SAs are to assure that surveys are conducted in 20% of the PRTFs in the state annually to validate the accuracy of the attestations and to investigate complaints. States should assume surveys will be conducted in 20% of the PRTFs annually as a tier 2 and ensure that PRTF recertification surveys are conducted at least every five years for each certified PRTF. Note: State survey costs (federal funds) for

this activity are provided through mandatory Medicaid funds. States should enter all PRTF attestations and provider agreements received from the State Medicaid Agency into the ASPEN system upon receipt. SAs should refer to the SOM, Chapter 2, section 2830 for more details on the certification process for PRTFs and State-to-State differences when accepting out of state admissions.

Also see https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/CertificationandComplianc/PRTFs.html and https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf

Survey & certification activities for PRTFs (Medicaid Psych < 21)

PRTFs must be in compliance with the requirements at 42 CFR 441.150-184 and the requirements at 42CFR 483 Subpart G

Priority tier structure for survey & certification activities for PRTFs (Medicaid Psych < 21)

Tier 1	Tier 2	Tier 3	Tier 4
Complaint investigations triaged as IJ.	**Complaint investigations triaged as non-IJ** **5-Year Interval**: In States with 5 or more PRTFs, 20% of PRTFs must be surveyed at least annually to meet 5-year interval (Complaint investigations don't count towards 20%).	N/A	**Initial Certification Surveys**

Contact Information

For questions, please contact: QSOG_PRTF@cms.hhs.gov

p. Religious Nonmedical Health Care Institutions (RNHCIs)

No new changes or efforts in FY2021. If changes arise, CMS will update this section as appropriate.

Contact Information

For questions, please contact: Survey Operations Group- Northeast at CMSBOSTONLTC@cms.hhs.gov

q. Transplant Program

The transplant program recertification survey interval has been changed to 5 years' maximum to be consistent with the hospital survey interval.
Due to the removal of the data submission, clinical experience and outcome requirements at § 482.82, the Transplant Program Quarterly Reports (TPQR) are no longer required or created to determine compliance during re-approval surveys.

Data submission, clinical experience and outcome requirements continue to be required for programs requesting initial approval as an organ transplant program. Initial transplant reports are available for each transplant program type to determine compliance with these requirements. State agencies should email the transplant mailbox at QSOG_TransplantTeam@cms.hhs.gov and request the report to obtain this information. Note: Organ transplant programs that have a clinical experience requirement must

have performed the required number of transplants before the initial survey is conducted. Reference § 482.80(d) for exceptions to this requirement.

Priority tier structure for survey & certification activities for Transplant Programs

Tier 1	Tier 2	Tier 3	Tier 4
Complaint – IJ: Investigation of complaint allegations triaged as IJ.	**Mandatory Re-approval Surveys:** 5 year survey interval.		**Initials: Any initial survey of programs**

Contact Information

For questions, please contact: QSOG_TransplantTeam@cms.hhs.gov

r. Core Infrastructure

Key Developments in training

To facilitate SA planning, we have provided updates below on key developments that will affect planning for training activities.

- Prerequisite for Basic Life Safety Code (BLSC) training:

  New SA Life Safety Code Surveyors will be required to obtain a "Certified Fire Inspector I (CFI-1)" certificate from the National Fire Protection Association (NFPA) certification program in order to attend the CMS BLSC course. NFPA no longer accepts CFI-1 certificates received from other courses. CMS does not require existing SA LSC surveyors to obtain a CFI-1 certification. In order to register for the CMS BLSC course, the SA must provide a copy of the NFPA CFI-1 certification to the CMS Quality Safety and Education Division for entry into QSEP. CMS does not require recertification of the CFI-1.

  The purpose of the CFI-1 is to ensure that all LSC surveyor candidates have a basic knowledge of fire protection and proficiency in the use of NFPA codes and standards as necessary to participate effectively in the BLSC course. The CFI-1 is based upon the NFPA Standard 1301, "Standards for Professional Qualification for Fire Inspector and Plan Examiners," which identifies the professional levels of performance required for fire inspectors, specifically identifying the job performance requirements necessary as a fire inspector.

  A candidate for NFPA CFI-1 certification must, at a minimum, have a high school diploma or equivalent. The NFPA CFI-1 certification program requires an exam and practicum to determine whether individuals have the requisite skills and knowledge. Passing the examination and completing the practicum are all that is required to obtain a CFI-1 certification, therefore NFPA training is optional for qualified applicants. The NFPA offers a paper and pencil exam after their training seminar as well as a computer-based examination at testing centers in all states and most territories. After successfully passing the examination, candidates will need to complete the practicum phase of the program in order to demonstrate the application of skills and knowledge. The practicum phase includes the completion of two mandatory and five elective occupancy survey exercises. It is possible that multiple practicum exercises can be completed during a state or supervised CMS-certification LSC survey, depending upon the size and type of facility.

CMS will not manage the acquisition of the NFPA CFI-1 certification for SA LSC surveyor candidates. SAs are responsible for addressing all matters necessary to obtain CFI-1 certifications for all SA LSC surveyor candidates who plan to attend CMS BLSC training.

Specific information on obtaining a NFPA CFI-1 certification can be found at: https://www.nfpa.org/Training-and-Events/Certification/Certification/Certified-Fire-Inspector-I

- Leadership Training:

  State survey agency Directors and Deputy Directors are required to attend and participate in the annual CMS Survey Executives Training Institute. This event typically requires 2.5 days of attendance and usually occurs in the Spring/Summer each year. Travel and lodging expenses are paid 100% from federal funds as an addition to the state's survey budget allocation.

ASPEN Data Entry of Survey Information (e.g. Completion and Use of the CMS-670)

It is important that accurate (e.g., survey coding) and complete survey data be available as soon as possible for any urgent follow-up actions or analysis. States must continue to ensure accurate and timely input and upload of information for the ASPEN system, including completion of the CMS-670 according to current ASPEN guidelines and CMS SOM Chapter 2, Section 2705 and evaluate their own surveyor times.

Quality Improvement Initiative

In FY 2003, CMS began publicly reporting nursing home, ESRD and home health quality measures and implemented a nationwide quality improvement effort in nursing homes and HHAs by Quality Improvement Organizations (QIOs). QIOs/ESRD Networks and SA partnerships are critical to the improvement of nursing home, ESRD and home health quality. In 2013, Networks and SA collaborated in two new areas, the Infection Control Initiative and the Involuntary Discharge Initiative. Networks and SA will continue to work together on the Fistula First Initiative.

Beginning in August of 2012, CMS launched a National Nursing Home Collaborative that focuses on preventable healthcare acquired conditions (HACs). As part of that initiative, the QIOs and their nursing home partners will work to strengthen the building blocks of change in order to help nursing homes make meaningful gains in the residents' quality of life and clinical outcomes. These building blocks may include but are not limited to staffing, operations, finance, and leadership among others. We fully support the QIOs in this endeavor and will continue to strengthen our partnership by aligning resources, encouraging collaborative participation and ensuring that each SA is a collaborative partner.

The core infrastructure requirement for quality improvement initiatives, applicable to all SAs, is focused on the following:

- Restraints, Pressure Ulcers, infection prevention and control, and Immunization Rates in Nursing Homes – Our mutual goal is to reduce the prevalence of pressure ulcers, reduce the incidents of restraints, infections, and increase the immunization rates in nursing homes.

- The SA's role is to:

  - Assure that State surveyors are adequately trained on the regulatory requirements and pertinent SOM interpretive guidelines;

  - Make sure that surveyors follow the survey protocols and processes;

  - Provide suitable enforcement remedies when nursing homes are cited;

- Provide appropriate communications and education for providers regarding the importance of these three priority areas, CMS' goals and resources available to nursing homes; and

- Coordinate S&C activities with those of the QIOs, make appropriate referrals to the QIOs and encourage systemic quality improvement in nursing home plans of correction.

- Working with Nursing Homes with Systemic Problems

  a. Meet requirements of the Special Focus Facility (SFF) initiative:
     - Select facilities to be designated as an SFF from the candidate list released periodically by CMS;
     - Survey SFFs twice every 12 months beginning from the date it is selected as an SFF;
     - Monitor SFF to determine if they meet graduation criteria or require more robust enforcement strategies.
  b. Coordinate with QIOs to provide nursing homes, which have systemic problems with possible tools to assist them.

- Staffing Data and Quality Measures (QMs) - With the help of SAs we are striving toward improving the adequacy of reported data for nursing home staffing data and QMs. The SA's role is to:
  - Ensure that surveyors follow survey protocols and processes in comparing survey and MDS information during the survey; and
  - Ensure that the RAI coordinator provides support and technical assistance for nursing homes in the coding of the MDS.
  - Monitor the accuracy of MDS coding and ensure that onsite surveys include a review of such coding.
- National Partnership to Improve Dementia Care in Nursing Homes: Launched in March 2012, the Partnership set a national goal of reducing the use of antipsychotic medications in nursing home residents by 15 percent. After achieving this goal in December 2013, CMS established new goals for reducing the use of antipsychotic medications in long- stay nursing home residents by 25 percent by the end of CY2015, and a 30 percent reduction by the close of CY2016 (using the original baseline rate established in Quarter 4, 2011). CMS is continuing to focus on reducing the use of antipsychotic medications through this initiative, such as working with a subset of nursing homes, identified as late adopters, who have had little to no improvement in their long-stay antipsychotic medication utilization rates. This multidimensional initiative includes transparency through public reporting; consumer, provider, prescriber, and surveyor education; research, interpretative guidance revisions, as well as quality improvement efforts involving partnerships with QIOs, National Nursing Home Quality Improvement Campaign. State Dementia Care Coalitions play a major role in sharing information, resources, data, and tools, conducting outreach with individual nursing homes, and engaging in educational programs with other agencies.

  Additional emphasis applies to working with nursing homes and QIOs on the implementation of culture change that improves quality of life, through the use of individualized, person-centered care approaches, without compromising quality of care.

Performance Management Activities

State budget submissions must include thorough and well-structured action plans for effecting Survey and Certification program goals and objectives. The plans should outline effective strategies for achieving performance targets and conforming to CMS' State performance standards and priorities. States should also identify how national goals and standards are being translated into individual

performance objectives. If CMS finds that the SA does not meet the performance standards, the SA will be expected to develop and implement a corrective action plan.

Nurse Aide Registry (NAR)/Nurse Aid Training and Competency Evaluation Program (NATCEP)

States are required to maintain a registry of all individuals who have completed a nurse aide training course and have passed a competency evaluation test. States must also investigate allegations of resident neglect and abuse (including misappropriation of personal funds) by a nurse aide or other individuals.

The State must assure that the nurse aide registry is operated in compliance with the Federal requirements. This includes assuring that:

- The SA reports findings of resident abuse, neglect and misappropriation of resident property to the registry and these findings are included in the registry within ten working days of the findings;
- In the case of a singular finding of neglect, the State has established a procedure so that a nurse aide can petition to have his or her name removed from the registry (The employment and personal history of the nurse aide must not reflect a pattern of abusive behavior or neglect and the nurse aide must wait one year from the substantiation of the finding before petitioning to have his or her name removed from the registry).

The allowable costs that can be charged to the Medicare State Certification program are outlined in Sections 1819(e) (1) and (2) of the Social Security Act. These costs relate to the State requirements to specify and review nurse aide training and competency evaluation testing programs together with the establishment and maintenance of the nurse aide registry. States are required to conduct these activities as part of the 1864 Agreement as authorized by Section 1864(d) of the Social Security Act. The actual training and competency evaluation testing of nurse aides are not payable as part of this Agreement.

See the General Budget Formulation Guidelines section of this letter for instructions on the reporting of NAR/NATCEP expenses and associated full-time equivalent amounts.

In September 2003, a final rule was published that creates a category of nursing home employee who may assist residents in eating and hydration. The SA may be involved with implementation if the State decides to allow the use of eating and hydration assistants. There may be State costs associated with implementation of this regulation.

Home Health Toll Free Hotline and Investigative Unit

States must maintain a toll-free hotline to receive complaints and to answer questions about HHAs. States must also maintain a unit to investigate complaints. CMS only pays for the maintenance of the hotline and complaint unit and for necessary survey or survey-related activity to follow-up on complaints regarding Federal home health agency requirements.

With the national implementation of ACTS in FY2004, States must ensure that complaints from the HHA hotline are effectively captured in ACTS.

Resident Assessment Instrument/Minimum Data Set (RAI/MDS)

All certified nursing homes and swing bed hospitals are required to encode and transmit MDS records to CMS via the Assessment Submission and Processing System (ASAP) in accordance with CMS established record specifications and time frames. As such, CMS expects the States to continue to provide staff to serve as RAI/MDS educational and technical resources to the nursing homes and SA in each State during the fiscal year, States must continue to adequately fund and staff the positions of a RAI coordinator and a RAI/MDS automation coordinator.

The State RAI coordinator and the RAI/MDS automation coordinators will be responsible for the following tasks:

- Attending all mandatory training sessions and demonstrating competency and skills in the RAI process, including coding and transmitting the MDS 3.0;
- Participating in CMS-sponsored workgroups and training including WebEx conferences, and satellite training programs for RAI Coordinators on the RAI process and the MDS 3.0.
- Conducting ongoing RAI/MDS education and training and providing technical support to SNF/NF and swing bed hospital providers and SA staff that--
  - Addresses the RAI process and proper coding of MDS elements to assist providers in meeting OBRA MDS and PPS requirements;
  - Incorporates the MDS 3.0, including any changes to the RAI, manual and survey processes.
- Includes at least two provider training courses annually, which may focus on basic RAI training for new providers or on topics identified either by the State or CMS as important for existing providers; administrative, educational and technical support to providers that will assist in the accuracy in coding of resident assessments; and the transmission of MDS data;
- The collection and housing of MDS data in order that States can develop and test a wide range of program improvement initiatives;
- Coordinating with CMS, SAs, FIs, A/B Medicare Administrative Contracts (MACs) and associations in their education of SNF/NF and swing bed hospital providers and surveyors regarding the MDS 3.0 and changes to the RAI, manual and survey processes;
- Conducting any follow-up training in conjunction with CMS national RAI/MDS educational offerings;
- Educating providers and SA staff on reports from the data system, MDS outcome reports, RAI Manual revisions and any revisions to the RAI process;
- Assist in promoting State-wide consistency with national policies and procedures; and
- Completing semi-annually reporting of the CMS MDS training worksheet in the QIES system in order to report the educational offerings that were conducted in the State during the year.
- Providing comprehensive education to RO & SA RAI and nursing home field-surveyor preceptors (RAI coordinators' conference and MDS 3.0 educational offerings – details to be announced in the MPD training addendum) so that these individuals can successfully manage provider and surveyor inquiries and issues related to the RAI and survey processes and the MDS 3.0. States should budget for the travel for this conference(s). See the MPD training addendum for greater detail on the intended audiences, timing and locations of the educational offerings; and
- Providing training and training aids for SA and RO training coordinators, field-surveyor preceptors and surveyors so that these individuals can successfully understand, interpret and implement the changes to the MDS and related survey processes.

As States will be responsible for assuring that their SA staff are trained in the use of the RAI process, including the MDS 3.0, as well as the changes to the SOM and survey reports and processes as a result of changes to the MDS 3.0, each SA will be responsible for its RAI and Automation Coordinators, as well as a nursing home field-surveyor preceptor, participating in the RAI Coordinators' Conference and MDS 3.0 educational offerings in the fiscal year, which may also include a series of webinars. States will also be responsible for ensuring that its RAI Coordinator(s) and survey and certification staff members collaborate in order to ensure that their SA staff are adequately prepared to perform their roles

as surveyors or RAI coordinators. This is particularly important as the MDS 3.0 significantly impacts both the RAI and survey processes.

States should note that MDS expenditures are reflected as long-term care Medicare and Medicaid costs on form CMS-435. For more reporting instructions, please refer to the General Budget Formulation Guidelines section.

HHA/Outcome and Assessment Information Set (OASIS)

All certified HHAs are required to encode and transmit OASIS records for Medicare and Medicaid beneficiaries to ASAP, in accordance with CMS-established record specifications and time frames. CMS expects the States to continue to play a key role in providing the educational and technical resources (CASPER) to the HHAs in each State. States will continue to fund the positions of the OASIS Educational Coordinator (OEC) and the OASIS Automation Coordinator (OAC) and will continue with the responsibilities outlined below:

The role of OECs includes:

- Basic OASIS training for new and existing providers;
- Educating providers and SA staff on reports from the data system and OASIS outcome reports;
- Provide CMS approved training materials as part of training activities for new and existing HHAs;
- Participating in CMS-sponsored workgroups and training when funding is available;
- Completing an annual OASIS training worksheet in the QIES system by October 15th of each year; and,
- Referring unresolved issues to the Home Health Quality Helpdesk (homehealthqualityquestions@cms.hhs.gov) for additional assistance.

The role of OACs includes:

- Providing ongoing technical assistance to HHA providers on the transmission of OASIS data.
- Referring unresolved issues to the QTSO Helpdesk for additional assistance.

Quality Improvement and Evaluation System (QIES) Automation Related Activities

In order to assess how information about OASIS, MDS and SB-MDS is disseminated across the nation, the States will report semi-annually on training and technical assistance that they have provided. Instructions for reporting training activity using the MDS and HHA Training Worksheets are found on the secure website: https://web.qiesnet.org/qiestosuccess/training.html. The worksheets are accessed via the QIES-To-Success website and are available to State personnel who have rights to see the MDS or HHA reports. The information entered on the worksheets is stored in the National Database. CMS Central and CMS Location personnel can retrieve this data via the CASPER reports: MDS Training Reports or HHA Training Reports.

With CMS technical support and guidance, States will be expected to continue to work closely with the provider community and their MDS, SB-MDS and OASIS software vendors to provide information on specific requirements related to the submission of MDS, SB-MDS and OASIS assessments especially with the move toward national implementation of the MDS 3.0, to the appropriate State or CMS repository. CMS expects that a facility's private sector software vendor will provide primary support to the facility in terms of MDS, SB-MDS and OASIS encoding and transmission. State personnel, however, will be required to work with facilities and software vendors to educate them about this

process. CMS has converted SNF and HHA providers to a virtual private network (Verizon Services) to meet confidentiality and security requirements.

However, each State must have one line accessible by CMS systems maintainers to ensure their system can be updated.

State personnel will continue to work with facilities and their software vendors in troubleshooting any difficulties facilities experience as they transmit records and implement MDS 3.0.

Each State should review its staffing requirements experience for support of State automation functions and recommend changes as needed. Staffing recommendations for systems support are listed in the "MDS/SB-MDS/OASIS/QIES System Support" section that follows further in this letter.

Each State should also review its State MDS and OASIS Automation Project Plans submitted with its prior year budget requests and provide any updates detailing continuing activities such as facility training, vendor and provider education and technical assistance to providers.

Reimbursement for MDS and OASIS Costs

Provider costs for MDS, SB-MDS and OASIS are compensated through the Medicare and Medicaid programs according to the rules for such reimbursement effective for Medicare and Medicaid.

CMS will continue to fund the cost of upgrading state computers needed to access the MDS and OASIS servers (discussed under Information Systems Hardware). Provider costs for hardware and software to maintain and transmit MDS, SB-MDS and OASIS data from their facility to the States will continue to be the provider's responsibility. States are expected to incur some costs associated with operating the MDS, SB-MDS and OASIS systems, specifically for staff time, training and supplies to support the automated QIES.

When States use MDS data in administering the Medicaid program, Federal costs associated with automating MDS and the operating data system should be apportioned by the States between two funding sources: the Medicare and Medicaid Survey and Certification program and the Medicaid program (under administrative costs). States should apportion MDS costs to these programs based on the States' determination of each program's utilization of the MDS system. Costs charged to the Medicare and Medicaid Survey and Certification Program will be prorated in terms of the portion of SNFs and NFs in the States that participate in the Medicare and Medicaid program. Similarly, costs associated with downloading and transferring SB-MDS data to the Medicaid program should be apportioned by the State between these two funding sources. The Federal match for the Medicaid Survey and Certification Program will be 75 percent. Budget estimates should be prepared and submitted as part of each State's Survey & Certification budget request.

Costs related to the publication, dissemination and validation of software vendors' ability to comply with State specifications for any added MDS, SB-MDS, or OASIS sections or data (i.e., that portion of the MDS or OASIS that may be added to the State's RAI or HHA instrument at the State's discretion) will not be funded through the Survey and Certification budget. To the extent that a State develops customized applications for information maintained in the OASIS database (e.g., to support Medicaid payment), the costs of developing and maintaining these additional software applications (and any related hardware components) will not be funded through the Survey and Certification budget.

We do not anticipate that any State will allocate more than a minimal amount of its MDS and OASIS costs to the Medicaid Program as administrative costs. The Federal match for costs apportioned as Medicaid administrative costs will be 50 percent and should be reported by the State on line 14 (Other Financial Participation) of the quarterly form CMS-64. Also, where State licensure programs benefit from the automation of the MDS and OASIS, the State itself should also share in the MDS and OASIS automation costs.

The Quality Improvement and Evaluation System (QIES)

CMS goals for the standardized MDS/OASIS/SB-MDS system go well beyond providing States with the ability to collect assessment data from providers and transmit that data to a central repository for analysis and support of prospective payment systems. CMS has always intended that the MDS/OASIS/SB-MDS data management system would support a suite of applications/tools designed to provide States and CMS with the ability to use performance information to enhance onsite inspection activities, monitor quality in an ongoing manner and facilitate providers' efforts related to continuous quality improvement. This overall initiative, known as the Quality Improvement and Evaluation System, also includes:

- Extension of the MDS/OASIS/SB-MDS systems to include new provider types in future years;
- Continued maintenance of the ASPEN suite of products (ASPEN Survey Explorer-Quality, ASPEN Central Office, ASPEN Enforcement Manager, ASPEN Scheduling and Tracking, and ASPEN Complaints and Tracking) and their integration with the state standard systems and support the migration to the new Internet Quality Improvement and Evaluation System (iQIES) that will replace the ASPEN suite of products; and,
- Further integration of the learning management system that supports most day-to-day operations of the survey and certification training program; and

CMS provides travel/training funds to assure that States are able to send two or three staff members to two, three-day train-the-trainer sessions for QIES/ASPEN systems releases and ASPEN each FY. These are mandatory training events and once trained, these trainers are expected to perform comparable, hands-on training for agency staff in each of these areas.

Quality IQIES/SB-MDS/MDS/OASIS State Systems Support

Each State must continue to provide adequate staff for technical systems support based on the staffing recommendations provided below.

FTE

Rank *	FTE	All Provider types/State (Excluding CLIA)
1	4.0	<600
2	4.5	600-1500
3	5.0	>1500

*These ranks may be adjusted upward if the RO believes the volume of a State's complaints warrant more staff.

These FTEs should be allocated approximately as follows:

- MDS/SB-MDS/OASIS Automation Coordinator - 1 FTE
- Systems Administrator - 0.5 to 1 FTE
- Technical operations/system management support - 0.5 FTEs
- Technical support/training for providers, vendors and SA staff - 1-3 FTEs distributed among MDS/SB-MDS/OASIS.
- ASPEN/QIES Coordinator - 1 FTE

These estimates reiterate CMS' staffing recommendations from prior MPD guidance. They do not represent new staffing requirements.

States should also examine their privacy and security controls and determine if optimum protections, as required by Federal and State standards, will necessitate any software, hardware, training, security protocols or budgetary adjustments.

- High Speed Internet Access (i.e., DSL, broadband, cable modem, T1)

The amount of data moved during each workday increases each year. Surveyor time is a precious asset and the amount of time involved in accessing information electronically is directly affected by the type of internet connection available. Back and forth communications between servers and clients can consume many megabytes per transaction. High speed connections also foster an environment where CMS and the SAs can optimize use of future uses of technology to improve survey efficiency, e.g., computer based training. Industry studies show that cost benefit analyses favor high speed connections and that is the direction in which the industry is progressing.

- Information Systems Hardware

The QIES system and components ASPEN are comprised of technologies that have been selected to deliver the most powerful access to a broad range of information related to facility quality monitoring and to support State agency survey operations within a user-friendly interface. While the core server components of the QIES system (i.e., hardware and software) are provided and installed by CMS within each State, additional computers for State agency end-users will be required to access this core system. These end-user systems are referred to as clients and include computers for users who work onsite within the State agency office as well as off-site users including facility survey staff. As the State QIES server assumes a larger role in day-to-day State operations, States should ensure that it is integrated into their existing systems infrastructure such as State LANs.

If SAs need to move the CMS QIES state servers to an alternate location, the SA will need to work with their CMS Location to include a $27,600 line item in their budget plan at the time of the move request (i.e., not waiting until the time of the move). So if a move is to take place at the beginning of the following FY, the funds would have to be made available in the preceding FY. This fee covers the move of the circuits and network support. The SA must submit a written request to the QIES Technical Support Office at a minimum of 90 days prior to the scheduled move date.

SAs currently vary in the number of laptop/notebook systems they have available for field surveyors' use in accessing ASPEN. Internally, most agencies provide network based computing support for in-house staff managers. Furthermore, over the past few fiscal years, many States have included extensive system upgrades as part of their budget requests.

CMS expects that States will use their existing systems to the fullest extent possible to provide client access to the standard system components. To provide users with access to the standard system, States should follow one (or a combination) of the following approaches:

a. Existing State machines that meet the minimum requirements, as described below, are used to provide user access to the standard system. This includes desktop systems connected to an internal network, as well as laptop/tablet systems used mainly for ASPEN Survey Explorer–Quality (ASE-Q).

b. To the extent that existing State systems do not meet the minimum requirements (e.g., insufficient RAM memory), the State submits a plan and budget request to support upgrading of these systems to the recommended performance levels, which includes the type of equipment to be purchased and associated costs. Upgrading an existing computer can include adding more RAM and disk capacity and purchasing processor upgrades. States should also include in the budget those costs associated with upgrading current computer operating systems to the prescribed Windows operating systems. The costs associated with upgrading equipment should not exceed the cost for actual replacement. Finally, it is also appropriate for States to include a budget for additional staff/contractor costs incurred to manage the computer and operating system upgrade process.

c. To the extent that a State does not possess sufficient systems that are currently capable or able to be upgraded to the minimum standard, the State should submit a plan and budget request to support the acquisition of the number of new systems that are necessary to provide appropriate access. The budget request must include the number of each type of machine to be purchased and associated costs.

d. Nursing Home Survey Process – CMS has moved towards a nursing home survey process, which utilizes Tablet technology. This technology allows ready access to data and information onsite by the surveyors and allows documentation of non-compliance to be easily transferred to the CMS-2567 form. CMS highly recommends that States plan for future survey process implementations as part of their hardware procurement process recognizing the need for Tablet PC configurations as a future need. The hardware that is budgeted by the SA is in addition to the hardware provided as part of the startup process, with the understanding that equipment costs will be distributed in the usual manner against Medicare/Medicaid/Licensure.

   Costs for equipment purchases that will be used in conjunction with any LTC survey process must be included on Form CMS-435 State Survey Agency Budget/Expenditure Report and CMS-1466 Survey and Certification State Agency Schedule for Equipment Purchases.

   Equipment purchases for LTC surveyors should include: one Tablet laptop (described in the table below, Minimum and Recommended Client Requirements) for each surveyor and one portable printer for every three such surveyors. The portable printers should be lightweight, capable of printing 17 pages or more per minute and capable of running on battery power alone.

e. Surveyor Technical Assistant for Renal Disease (STAR) - Prior to attending a STAR training course, surveyors are expected to have access to specified tablet PCs. Surveyors will be able to use the same Tablet equipment for QIS and STAR.

Guidelines for the recommended system configuration and State size based estimates for the number of systems required are found below. For planning purposes, it is expected that at least 10 client systems will be required for in-office access to the standard system and related components, based on State size (i.e., small, average, large). In other words, a large State should have 30 client systems that meet the minimum standards for agency staff. For field systems, States should seek to maintain a ratio of at least one laptop/tablet system per two surveyors.

a. Laptops:

Recommended field system is any Windows 7 or Windows 8 computer designed for light-weight portability and provides both a keyboard option and an option to operate the device as a flat tablet. ASPEN software operates on traditional laptop computers with no flat tablet mode but this is less optimal for field use, especially for QIS surveyors. Any selected surveyor computer must also meet the required technical specification provided.

b. Encryption Policy

CMS' encryption policy requires all agency data be protected from unauthorized access. There may be various levels of protection for agency data, but for personally identifiable information (PII), the policy states that dissemination of such data using any portable devices or recordable media, (e.g., CDs, DVDs, Cartridges, Diskettes, Laptops, External Hard Drives, USB Memory Sticks or thumb drives, etc.), requires encryption. Whole disk encryption of the hard-drive for Laptops or Tablet PCs must be employed.

Encryption is the process of protecting stored or transmitted information with a password (key) so that it is indecipherable until the intended recipient uses the password to access it.

In accordance with the CMS encryption policy, all workstations with installed QIES components must have encryption software installed that meets or exceeds the standards set forth in the "CMS Information Security Acceptable Risk Safeguards (ARS)" This includes all QIES components installed on Laptop/Tablet PCs as well as any removable media and/or cloud computing used to disseminate PII/PHI. Specifically, the following sections of the ARS should be referenced:

- IA-7 Cryptographic Module Authentication (Specifies acceptable encryption type – FIPS 140-2 compliant (http://csrc.nist.gov/publications/PubsFIPS.html) NIST validated module. (http://csrc.nist.gov/groups/STM/cmvp/index.html)
- IA-2 User Identification and Authentication
- AC-3 Access Enforcement
- AC-4 Information Flow; specifically CMS-2
- AC-19 Access Control for Portable and Mobile Systems (encryption requirement only)
- MP-5 Media Transport
- SC-8 Transmission Integrity
- SC-12 Cryptological Key Establishment and Management

Please note, in addition to these encryption sections, agencies are encouraged to review the entire ARS as a guideline for enterprise-wide security practices. States are responsible for ensuring that encryption software has the capability of creating encrypted files that are self-extracting with a password key.

Additionally, many agencies have home-based staff using QIES software installed on home workstations. Such home-based systems must be protected with encryption software as described above and comply with CMS controls as defined in the ARS.

Minimum and Recommended Client Requirements: EXISTING or NEW EQUIPMENT

Component	Minimum	Minimum or Higher Required for LTC Survey Process Implementation Recommended for Other
Processor	Pentium Class (or equivalent) @ 1.2 GHz	Pentium Class (or equivalent) @ 2.0 GHz
Memory (RAM)	2 GB	4 GB
Available Disk Space	4 GB	10 GB on SATA 2 drive at 7200 RPM
Monitor	13" Color	Desktop 19": Color Flat Panel ≥1024x768 screen resolution Flat Panel for laptop or tablet
*Operating System**	Windows 7 – 32 bit Windows 7 – 64 bit	Windows 7 – 32 bit Windows 7 – 64 bit Windows 8.1 – 32 bit Windows 8.1 – 64 bit Windows 10 – 32 bit Windows 10 – 64 bit
Secure Access/Encryption (See Encryption Policy)	Required – See Encryption Policy	Required – See Encryption Policy
Anti-virus	Current License	Current License
Universal Serial Bus Port	One	Three
Removable Media (see Encryption Policy)	USB Drive	USB Drive
Pointing Device	Mouse or equivalent (e.g. trackball or touchpad)	Mouse or equivalent (e.g. trackball or touchpad) and Pen/Stylus
Network Interface Card *(See CMS ARS security guidelines for acceptable wireless configurations)*	Wired for network connectivity; and Wireless network cards must support WPA-2 level encryption	Wired for network connectivity; and Wireless network cards must support WPA-2 level encryption
Optical Drive	CD –ROM	CD/DVD-ROM (External for tablet)
Minimum and Recommended Client Requirements: EXISTING or NEW		

EQUIPMENT		
Component	**Minimum**	**Minimum or Higher Required for LTC Survey Process Implementation Recommended for Other**
Audio	Standard built-in speakers	Attachable microphone and standard built-in speakers
Battery (laptop or tablet)	6-cell lithium-ion	6-cell lithium-ion
*Browser***	Internet Explorer v 11.0	Internet Explorer v 11.0

* States considering implementing Windows 10 should carefully evaluate CMS software with this Operating System before full scale deployment.

Note: Operating systems need to be current with all Windows security updates.

**Internet Explorer v 11 will need to operate in compatibility mode in order for the software to operate properly.

Per the Internet Explorer Support Lifecycle Policy FAQ (https://support.microsoft.com/en-us/gp/microsoft- internet-explorer), beginning January 12, 2016, only the most current version of Internet Explorer available for a supported operating system will receive technical support and security updates.

As of January 1, 2016, Internet Explorer v 9.0 and v 10.0 is no longer supported. Only Internet Explorer v 11.0 running in compatibility mode is currently supported.

Due to new CMS security requirements, all browsers must have the TLS 1.2 setting enabled.

Emergency Preparedness

SAs operate in a larger context of State emergency preparedness and often play important roles within a State Incident Command System (ICS) that extend far beyond federal survey and certification functions. In such cases States have cost accounting systems in place to allocate expenses properly and ensure that the cost of non-federal activities is not charged against federal accounts. Nonetheless, some emergency preparedness and emergency response activities are vital to the effective conduct of federal quality assurance and, as such, are properly included in the State's S&C mission, priority and budget document.

The items identified below are key elements that have been developed based on the recommendations of the S&C Emergency Preparedness Stakeholder Communication Forum. While we realize some States already have very well-developed systems that far exceed the elements described here, we appreciate that for many States enhanced IT reporting capabilities require additional time to implement. In September 2007, CMS, therefore provided considerable advance notice for States to establish the electronic tracking and reporting capability no later than July 1, 2009 that includes the data elements identified under "2. Effective Communication & Coordination with CMS."

1. SA Continuity of Operations (COOP)

The SA maintains a coordinated, emergency Continuity of Operations Plan (COOP), updated at least annually, which is submitted to the CMS Location. The COOP addresses:

a. Essential S&C business functions, including:

- Provision of prompt responses to complaints regarding patients/residents who are in immediate jeopardy.
- Provision of monitoring and enforcement of healthcare providers. Even in widespread or significant disasters where reduced S&C activities may occur, key activities (such as complaint investigations, provider communications, communication with CMS regarding any advisable adjustment to previously- imposed enforcement actions that might impede evacuee placement, etc.) will still need to occur in order to ensure the health and safety of patients and residents.
- Conducting timely surveys or re-surveys in the aftermath of a disaster.

b. Identification of strategies to ensure maintenance and protection of S&C critical data.

c. A program of COOP exercises, conducted at least annually by designated staff to ensure State, Regional, Tribal and Federal responsiveness, coordination, effectiveness and mutual support.

2. Effective Communication & Coordination with CMS

a. Point of Contact: A State S&C emergency point of contact (and back-up) is available 24 hours per day and 7 days per week to the CMS Location when the State declares a widespread disaster. The contact:

- Coordinates State S&C activities with CMS;
- Addresses questions and concerns regarding S&C essential functions;
- Provide status reports; and
- Ensures effective communication of federal S&C policy to local constituencies (see details below).

These functions may be fulfilled by a person within the State ICS who has been clearly assigned to communicate with CMS and provide data for S&C functions.

b. Policy Communications: The SA maintains capability for prompt dissemination of CMS policy and procedures to surveyors, providers and affected stakeholders. During a disaster, the capability is operative 24/7. The SA capability includes back- up communication strategies, such as websites and hotlines and emergency capability that enable functional communication during energy blackouts. A designated person is available for responding to healthcare providers' questions and concerns related to federal survey and certification. These functions may be performed by a person within the State ICS, who has been clearly assigned to perform these functions.

c. Information and Status Reports: The SA or the State ICS maintains capability and operational protocols to provide the CMS Location with (a) State policy actions (such as a Governor's

emergency declarations or waiver of licensure requirements) and (b) an electronic provider tracking report, upon request, regarding the current status of healthcare providers affected by a disaster. The capability includes:

Provider Contacts	Provider Status	Provider Plans
• Provider's name • CMS Certification Number (CCN) • National Provider Number (NPI) • Provider type	• For profit/ or not-for-profit agency, or government agency status • Provider status (evacuated, closed, damaged) • Provider census • Available beds	• Estimated date for restored operations • Source of information • Date of the status information
• Address (Street, City, ZIP Code, County) • Current emergency contact name • Contact's Telephone number and alternate (e.g., cell phone) • Contact's email address	• Emergency department contact information (name, telephone number, FAX number) if different than provider contact information • Emergency department status (if applicable) • Loss of power and/or provider unable to be reached	

Recovery Functions

Recovery functions will be determined on a case-by-case basis between the SA and the CMS Location. In the context of survey & certification, recovery functions represent those activities that are required to ensure that a provider has re-established the environment and systems of care necessary to comply with Federal certification requirements.

Funding

We believe that the types of actions that we are specifying are currently underway or in place based on State-level initiatives and/or prior informal arrangements between States and CMS Locations formed on an ad hoc basis. In many of these cases, implementation costs will be very low. We, therefore, encourage SAs to seek other available sources of emergency services funding or grants to promote emergency preparedness coordination wherever possible and to share information and expertise with other States.

To the extent that routine work cannot be accomplished during a significant disaster, unobligated S&C funds may be available to provide fiscal resources that otherwise could not be budgeted for the above activities. Depending on the nature of the disaster, the CMS Location may also authorize expenditures for certain recovery efforts that would not normally be covered, when such activities advance the subsequent recovery and the continued or resumed certification of providers. An example is the conduct of pre-survey site visits in the aftermath of a disaster, prior to the reopening of a healthcare facility, particularly when the result of the site visit is a conclusion that a subsequent survey is not required (such as a finding that damage is so light that a new life-safety code survey is not needed).

If a very significant emergency occurs in a State and it calls upon extra SA resources to meet the resulting needs, the State can submit a supplemental budget request, which we will consider for priority funding depending on the severity and extent of the emergency.

States are still required to submit electronic affected provider status reports to the CMS Location during emergency events, which include the data elements identified above. An Affected Provider Status Report template is available on the S&C Emergency Preparedness website for this purpose: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep/StateAgencyGuidance.

Relationship to State Performance Standards System (SPSS)

If a significant emergency occurs in a State that disrupts normal survey and certification activity and that is well outside the level that can typically be expected in the State, CMS will take such circumstances into account so as to avoid penalizing the State for SA Performance issues unavoidably caused by the emergency.

Energy Productivity

Consistent with the President's policies and executive direction, CMS seeks to improve the energy productivity of survey & certification operations. Insofar as transportation and fuel costs are significant items of S&C expense, we encourage States to lease or modernize their automobile fleets with highly efficient vehicles that meet or exceed 40 miles per gallon in combined city/highway EPA mileage ratings. An increasing array of vehicles meets this level of efficiency. We will continue CMS incentives to enlarge upon transportation and other energy productivity improvements. In the event that one-time funding becomes available later in the FY, we suggest that States conduct some advance analysis of what would be feasible to take advantage of such funds and how the State would accomplish appropriate cost-accounting among affected funding sources if Medicare one-time funds were available.

Alignment with SPSS

States must maintain documentation and information systems to ensure accurate and timely provision of information on survey activities, findings, enforcement and surveyor performance. Timely uploading of surveys is an important aspect of such a system. With regard to performance of surveys within the required frequencies, most non-LTC provider types continue to be part of the SPSS for frequency of surveys specified in tiers 1-3. The SPSS includes all of the following with regard to survey frequency.

Table: Providers/Suppliers for which tier 1-3 Performance is Measured by SPSS

Statutory Providers	Other Providers
• Nursing Homes • Home Health Agencies • Hospices • Validations – all types of deemed providers/suppliers • ICFs/IID	• Hospitals (all types) • ESRD facilities • Rural Health Clinics (RHCs) • ASCs • OPTs (Rehabilitation Agencies) • Comprehensive Outpatient Rehabilitation Facilities (CORFs)

States must track their tier workload on a quarterly and annual frequency. During the course of the year, States must report the quarterly results to the CMS Locations by the end of the month following the end of the quarter. As part of their oversight and trouble-shooting responsibilities, CMS Locations will be monitoring and working with the States on the performance of the tiered workload.

Priority tier structure for survey & certification activities of Core Infrastructure

Tier 1	Tier 2	Tier 3	Tier 4
Timely ASPEN data entry of survey workload Attendance at mandatory federal surveyor training MDS, OASIS, QIES and IRF-PAI systems activities Maintenance of the nurse aide registry and assessments of nurse aide training and competency evaluation programs Review of the nurse aide registry to assure that it is being operated in compliance with the requirements. Maintenance of a home health hotline Performance Measurement Activities Implement & promote fulfillment of CMS GPRA goals and Quality Initiative, including collaboration with QIOs on the GPRA goals (pressure ulcer reduction, restraint use reduction). Training of survey & certification staff, including transcript & qualifications maintenance. Emergency preparedness essential functions.	N/A	N/A	N/A

Contact Information

For questions, please contact the appropriate program area:
QSOG_ASC@cms.hhs.gov;
QSOG_CORF@cms.hhs.gov;

HHAsurveyprotocols@cms.hhs.gov;
QSOG_Hospice@cms.hhs.gov;
QSOG_OPT@cms.hhs.gov;
CMSQSOG_PXR@cms.hhs.gov
QSOG_RHC-FQHC@cms.hhs.gov;
QSOG_Hospital@cms.hhs.gov
QSOG_TransplantTeam@cms.hhs.gov
QSOG_ESRDQuestions@cms.hhs.gov
QSOG_PsychiatricHospital@cms.hhs.gov
QSOG_PRTF@cms.hhs.gov
QSOG_ICFIID@cms.hhs.gov
CMHC@cms.hhs.gov
QSOG_CAH@cms.hhs.gov

s. Clinical Laboratory Improvement Amendments of 1988 (CLIA)

CLIA regulates the quality and safety of U.S. clinical laboratories to ensure the accuracy, reliability, and timeliness of patient test results regardless of where the test was performed. CLIA has regulatory requirements for quality that all laboratories must meet.

Definition of a Laboratory

A clinical laboratory is defined by CLIA any facility which performs laboratory testing on specimens obtained from humans for the purpose of providing information for health assessment and for the diagnosis, prevention, or treatment of disease.

Accreditation Organizations with CMS-Approved Programs

Currently there are 7:

- American Association for Laboratory Accreditation (A2LA)
- American Association of Blood Banks (AABB)
- American Society for Histocompatibility & Immunogenetics (ASHI)
- Collage of American Pathologists(CAP)
- COLA, Inc. (COLA)
- Healthcare Facilities Accreditation Program (HFAP)
- The Joint Commission (TJC)

CLIA Certificates

Certificate of Waiver (COW): Issued to a laboratory that only performs waived tests.

Certificate for Provider Performed Microscopy Procedures (PPMP): Issued to a laboratory in which a physician, midlevel practitioner, or dentist performs only specifc microscopy procedures during a patient's visit. See list of PPMP procedures, which are a subset of moderate complexity tests.

Certificate of Registration (COR): A COR is temporary and permits the laboratory to conduct non-waived (moderate and/or high complexity) tests until the laboratory is inspected and found to be in compliance with CLIA regulations.

Certificate of Compliance (COC): Issued to a laboratory after an inspection by a CLIA state survey agency that determines the laboratory to be in compliance with all applicable CLIA requirements.

Certificate of Accreditation (COA): Issued to a laboratory on the basis of the laboratory's accreditation by an accreditation organization approved by CMS.

CLIA Resource Information

CLIA Regulations – CLIA Regulations 42 CFR 493[21]
Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services[22]

Priority QSOG Activities for Laboratories

CLIA is a user-fee funded program which requires that the following surveys will be prioritized throughout the year as needed:

- Complaint
- Validation
- Recertification
- Initial

Contact Information

For questions, please contact: LabExcellence@cms.hhs.gov

t. Additional priority tier structure for survey & certification activities

Priority tier structure for survey & certification activities for New Provider Initial Surveys

Tier 1	Tier 2	Tier 3	Tier 4
Initial certification of the following: • ESRD Facilities	Relocations of the parent or main location of existing non-deemed providers or suppliers. Relocations of any provider/supplier displaced during a public health emergency declared by HHS.	Initial certification of the following: • Transplant Programs • SNF/NFs Relocations of non-deemed branches or off-site locations. Note: Conversion of a non-deemed hospital to a CAH, or a non- deemed CAH back to a hospital is a conversion, not an initial certification and at state option may be done as tier 2, 3, or 4. However, the conversion of a deemed hospital or CAH or the addition of swing beds as a new	Initial certifications of all provider/supplier types that have a deemed accreditation option (with the exception of ESRD): hospitals, home health, new home health branches, hospice, expansion of inpatient hospice for a currently certified hospice, ambulatory surgical centers, outpatient physical therapy, and rural health clinics. While CAHs may also be deemed, these are conversions, not initial certifications; however, deemed CAHs are

[21] https://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5
[22] https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107ap_c_lab.pdf

		service in an existing deemed or non-deemed hospital or CAH is a tier 4 priority.	expected to be surveyed by their AOs for their conversion surveys.) The addition of home health branches are administrative actions thus not a deeming option. (AOs deem compliance with CoPs/CfCs, not administrative actions.) Though surveys may not be involved, these actions should remain in the tier structure as they are often resource intensive. The addition of hospice multiple locations may warrant a survey. These surveys should be scheduled consistent with the tier structure as they are often resource intensive. All other newly-applying providers not listed in tier 3 are tier 4, unless approved on an exception basis by the CMS Location, due to serious healthcare access considerations or similar special circumstances. Relocations of deemed providers or suppliers

Contact Information

For questions, please contact the appropriate program area:

QSOG_ASC@cms.hhs.gov;
QSOG_CORF@cms.hhs.gov;
HHAsurveyprotocols@cms.hhs.gov;
QSOG_Hospice@cms.hhs.gov;
QSOG_OPT@cms.hhs.gov;

CMSQSOG_PXR@cms.hhs.gov
QSOG_RHC-FQHC@cms.hhs.gov;
QSOG_Hospital@cms.hhs.gov
QSOG_TransplantTeam@cms.hhs.gov
QSOG_ESRDQuestions@cms.hhs.gov
QSOG_PsychiatricHospital@cms.hhs.gov
QSOG_PRTF@cms.hhs.gov
QSOG_ICFIID@cms.hhs.gov
CMHC@cms.hhs.gov
QSOG_CAH@cms.hhs.gov

Priority tier structure for survey & certification activities for Complaint Investigations

Tier 1	Tier 2	Tier 3	Tier 4
Complaint Investigations triaged as a high potential for immediate jeopardy or, in the case of hospitals, psychiatric hospitals or CAH DPUs, where the CMS Location authorizes investigation of a hospital or CAH DPU restraint/seclusion death incident. For all deemed non-LTC provider/supplier types for which one or more condition-level deficiencies is determined to be out of compliance pursuant to a complaint investigation, the CMS Location: • May require a full survey before proceeding to enforcement.	Complaint Investigations triaged non-IJ high.	Complaint investigations of non- deemed non-LTC facilities triaged as non-IJ medium are investigated when the next on-site survey occurs. Complaint investigations of LTC facilities triaged as medium	Complaint investigations of LTC facilities triaged as low Complaints of non-deemed non-LTC facilities triaged as non-IJ low are not separately investigated but tracked/trended for potential focus areas during the next on-site survey.

Contact Information

For questions, please contact the appropriate program area:

QSOG_ASC@cms.hhs.gov;
QSOG_CORF@cms.hhs.gov;
HHAsurveyprotocols@cms.hhs.gov;
QSOG_Hospice@cms.hhs.gov;
QSOG_OPT@cms.hhs.gov;

CMSQSOG_PXR@cms.hhs.gov
QSOG_RHC-FQHC@cms.hhs.gov;
QSOG_Hospital@cms.hhs.gov
QSOG_TransplantTeam@cms.hhs.gov
QSOG_ESRDQuestions@cms.hhs.gov
QSOG_PsychiatricHospital@cms.hhs.gov
QSOG_PRTF@cms.hhs.gov
QSOG_ICFIID@cms.hhs.gov
CMHC@cms.hhs.gov
QSOG_CAH@cms.hhs.gov

VI. Budget Formulation Guidelines

Continued Mission Directive for FY 21

CARES Act

The Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (P.L. 116-136) was signed into law by President Trump on March 27, 2020. The legislation provided supplemental Medicare funding of at least $100,000,000 to fund Survey and Certification activities related to COVID-19 response, prioritizing nursing homes in locations with coronavirus community spread. Of this amount, we expect to provide State Survey Agencies (SAs) approximately $81 million for such certification costs and services performed under section 1864 of the Social Security Act. This funding is available through September 30, 2023.

CMS will follow an annual budget and award process lasting each year through FY 23 for supplemental funding. SA funding awards will be reconciled at the end of each year to ensure effective use of funds through its entire period of availability and will allow for fully justified, reasonable supplements, if needed.

For Medicare expenditures, CMS Headquarters (HQ) is implementing a reporting process similar to the existing MDS and HHA reporting processes to allow for appropriate tracking of CARES Act funds. The allowable usages of the CARES Act funds as well as the process to receive these funds are detailed in Admin Info memo 20-07-All (Revised)[23]. Cost sharing will continue according to existing State practice.

For Medicaid expenditures, COVID-19 expenditures will be tracked and reported separately; however, funding will continue to be provided via traditional means in accordance with Title XIX of the Social Security Act. Cost sharing will continue according to existing State practice.

It should be noted that all CARES Act funds need to be reported separately on the mini CMS 435 - COVID-19 form utilizing the standard cost allocation methodologies. However, these Medicare CARES Act funding amounts should be included on the main CMS 435 on a separate Miscellaneous line labeled CARES Act.

Continued Title XVIII Budget Closeouts

[23] https://www.cms.gov/files/document/admin-info-20-07-all-revised.pdf

With the passage of the Grants Oversight and New Efficiency Act (GONE, P.L. 114- 117), a focus has been placed on properly following and executing existing FY budgetary closeout processes. This focus is not in any /way intended to add existing work to State Agencies, in fact, this focus should help States be able to close out their financial books sooner rather than sometimes waiting for 5 years after the close of the FY.

- **Budget Closeout Requirements:** The main goal is to establish a common grants closeout process in-line with current Departmental regulations, statute and audit recommendations. With respect to the states, this will primarily be a change to the timeframes involved in closeout, the possibility for unilateral closeouts, as well as an increase in emphasis on closing awards in a timely manner. The actual work required to effect a proper closeout will remain substantially the same.

The timelines for this process are as follows:

- Final financial reports, consistent with terms of award, are due 90 calendar days from a grant's completion date;
- Full closeout, meaning that all applicable administrative actions and all required work of the federal award have been completed and takes actions as described in 45 CFR 75.381, is due no later than 270 days from a grant's completion date;
- If the closeout cannot be completed within the 270 day timeframe, CMS **may** elect to complete a unilateral closeout.

CMS Baltimore will provide states sufficient notification of upcoming due dates for both report and closeout due dates via written memorandum and email notification, and will work with states to meet the due dates noted. CMS Baltimore will work with states on a case-by-case basis if there are reasons that they are unable to meet the guidelines noted above.

Continued Budget and Expenditure Reporting Timing and Requirements

The S&C program may operate under the terms and conditions of a Continuing Resolution, with funding based on the previous FY base budget as noted in Appendix 1, column A, until such time that Congress passes a final appropriation containing S&C funding. Please note, we are currently assessing our budget execution process in order to provide funding assumptions and budgetary information as early as we can. We will provide updated timeframes as they become known. For planning purposes, current timeframes for the budget process are as follows:

Jan - March – States submit, with justification, requested changes to their proposed FY budget amount listed in Appendix 1 to the CMS Locations, in accordance with the Admin Info Memo issued each year.

CMS Locations complete review of the States appeal submissions and offer recommendations, by state, to the CMS Baltimore (Bary.Slovikosky@cms.hhs.gov).

Jan - April – CMS Baltimore staff will hold conference calls with the CMS Locations to discuss and make final decisions regarding the FY 21 Allocations.

Feb - April – Final allocations are determined and communicated to states.

March - May – States submit the final budget package and plans to CMS locations, including updates to the CMS 434-Planned Workload form, using the CMS tier priorities. For the final budget package, each state's budget should be based on a specific dollar amount expected for Medicare funding (rather than a general estimate of what the state believes is needed).

Again, these timelines are for planning purposes and may be subject to change based when Congress passes a final budget appropriation.

IMPACT Act Budget

Beginning in FY 18 and continuing through FY 25, the amount of annual IMPACT funding available has been reduced over the level provided in FY 15-FY 17. To account for this difference, funds to cover the shortfall have been set aside to allow the SA's to have enough funding to complete the statutory work. The final IMPACT funding amounts will be made available once all of the SA requests have been received for the FY (typically should be in December of the current FY). Reporting of this funding should be as follows:

All Hospice funds, whether IMPACT or non-IMPACT, should be reported separately on the mini CMS 435 Hospice form. However, as a reminder, IMPACT funding amounts **should not** be included on the main CMS 435, while any SA receiving additional funding, non-IMPACT, for Hospice work **should** report those costs on the main CMS 435 on a separate miscellaneous line. Please identify the separate line as "Additional Hospice Funding". If a state sees any significant issues with its allocation, or has questions about the allocations or cost accounting, please communicate those promptly to your CMS Location.

MDS and HHA mini CMS 435 forms

The MDS mini-CMS-435 includes all MDS related costs while the HHA mini-CMS-435 should include all HHA and OASIS costs. This budgeting (and subsequent expenditure reporting) will show the subset of all MDS and HHA-related costs that **are** included in the full CMS- 435 form.

HHA Cost Allocation

States should use a simplified 50% Medicare-50% Medicaid method to share the federal costs (after state licensure costs are accounted for) by:

1. Identifying the total cost of HHA surveys,
2. Subtracting the state-only amount that reflects the state licensure share,
3. Dividing in half the remainder (total federal share of HHA costs) and
4. Assigning one half to Medicare and the other half to Medicaid.

Please refer to S&C Memo 13-31-HHA[24], dated May 17, 2013, for more detail.

State Licensure Shares

This information is required to be filled into columns G & H of the CMS 435 as part of the budget reporting package. This information is necessary to adequately review the use of proper cost accounting to ensure appropriate cost sharing across all funding sources of the Survey & Certification program.

NAR/NATCEP Costs

States must continue requesting and reporting all Medicare NAR/NATCEP costs on the Miscellaneous line 19A of the form CMS-435. These expenses are not to be included in salaries/fringe benefits. States' budget requests should be tied to the number of nurse aides and/or training programs. All budgets must include NAR/NATCEP expenses under line 19A (Miscellaneous) on the form CMS-435 (column B).

- NAR/NATCEP and competency evaluation costs incurred for Title XIX-only facilities are considered administrative costs and are to be reported on the Quarterly Medicaid Statement of

[24] https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-31.pdf

Expenditures for the Medical Assistance Program (form CMS-64). There are no provisions for covering these expenses in the Medicaid Survey and Certification budgets.

- Costs incurred in joint Titles XVIII/XIX facilities for NAR/NATCEP will be charged and reimbursed 50 percent by Medicare and 50 percent by Medicaid (50%-50% split). Expenses incurred for Title XVIII should be reported on the form CMS-435; expenses for Title XIX on the form CMS-64.
- Guidance pertaining to allowable NAR/NATCEP expenditures can be found in Chapter 4 of the State Operations Manual (SOM).

Training Line on CMS-435

Under no circumstance, should the costs reported in the training line on the form CMS-435 be zero. As discussed in the SOM, this line item includes **any** non-salary costs associated with training.

Final Budget Package

In summary, the final budget package should include:

1. Main CMS-435 Budget Request Form; *Note: This form should capture all projected FY 21 expenditures (including MDS and HHA/OASIS, but not including IMPACT Act Hospice costs) spread across the appropriate lines of the CMS-435.*
2. Mini CMS-435s for MDS and HHA/OASIS (subset reports of the main CMS-435);
3. CMS-435 IMPACT Act – Hospice (separate report), with projected expenditures spread across the appropriate line items;
4. CMS-434 Planned Workload Report;
5. CMS-1465A Budget List of Positions;
6. CMS-1466 Schedule for Equipment purchases;
7. Budget narrative with work plan and line by line justification;
8. Include a single, all-inclusive tier Statement: indicate what tier workloads the state will and will not be able to accomplish. If circumstances allow for only partial completion of a particular tier workload, indicate in the tier statement which work will not be completed in the tier, by provider type, and the extent of the survey work that the state expects it will be unable to accomplish. Please recall that there is a triage level of complaint investigations in each tier, so mention those if they come into play;
   Please make a tier statement as a clearly identified paragraph toward the top of the budget narrative. It can be as simple as “tiers 1, 2 and 3 will be done, but not initial surveys in tier 3 and tier 4.” Or the statement can be more detailed, especially if the state will complete part of a tier, and needs to specify what won’t be done in the tier;
9. Most recent Indirect Cost Agreement.

CMS Budget Analysis and Adjustment

CMS’ CO will continue to partner with the CMS Locations to review and agree upon a final budget amount for FY21 for each state once Congress has finalized a budget. The funding available to states will be allocated based on several factors that are taken into account such as:

1. Historical Spending;
2. Workload Requirements;
3. State Hiring Challenges.

It is recommended that states make the CMS Locations aware of expected funding shortfalls or overages as soon as possible in FY 21 to ensure that the most effective funding distribution can be made as soon as Congress passes a budget.

Due to the reduced level of IMPACT funding which started in FY 18, an analysis of all state requests will encompass previous FYs actual spending level vs. the current FY request before final IMPACT awards are determined.

Contact Information

For questions, please contact: Your CMS Location budget staff

VII. Quality, Safety & Education Division (QSED)

a. Mission

The mission of QSED, in partnership with CMS Locations and SAs, is to ensure a knowledgeable and skilled survey workforce and informed providers and suppliers throughout the United States. QSED provides leadership and oversight for the design, development, and delivery of all surveyor training and testing, to actively support the mission of CMS and Department of Health and Human Services (HHS).

b. Statutory Authority

The Social Security Act (The Act) obliges the HHS Secretary to "provide for the comprehensive training of State and Federal Surveyors in the conduct of standard and extended surveys". The Act requires that "No individual shall serve as a member of a survey team unless the individual has successfully completed a training and testing program in survey and certification techniques that has been approved by the Secretary." It mandates the "Secretary of HHS, through the CMS Administrator, [will] assure that surveyors are trained to make determinations about the Conditions of Participation (CoP) of providers", as well as the Conditions for Coverage/Certification (CfC) for suppliers.

Authority: Section 1819G of the Social Security Act. Related authority: US Code, Section 1396 – 1396v, Subchapter XIX, Chapter 7 and Title 42. And Chapter IV, Title 42, and Title 45, Code of Federal Regulations, and Section 1919(g), "Survey and Certification Process," subparagraph (iii).

c. Survey-specific Training

QSED's comprehensive training programs are designed to empower SA and CMS Location surveyors with the knowledge, skills and abilities needed to conduct a survey in accordance with the CMS conditions and standards. QSED plans, manages, and executes training for approximately 10,000 surveyors who survey different types of health care facility providers and suppliers. QSED provides specialized surveyor training for the following survey processes:

- Ambulatory Surgery Centers (ASC)
- Critical Access Hospitals (CAH)
- Clinical Laboratory Improvement Amendments (CLIA)
- Community Mental Health Centers (CMHC)
- End-Stage Renal Disease (ESRD)
- Home Health Agencies (HHA)
- Hospice
- Hospitals, including:
- Emergency Medical Treatment and Labor Act (EMTALA)
- Psych Hospitals
- Transplant
- Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID)
- Life Safety Code (LSC)
- Long Term Care (LTC)
- Outpatient Physical Therapy or Outpatient Speech Language Pathology Services (OPT/OSP)

- Psychiatric Residential Treatment Facilities (PRTF)
- Rural Health Clinics (RHC) & Federally Qualified Health Centers (FQHC)
- Organ Procurement Organizations (OPO)

QSED's training programs include a series of structured, organized training activities designed to help surveyors obtain the knowledge, skills, and abilities they will need to conduct a survey in accordance with CMS policy. The first series of training activities lay a solid foundation of knowledge. Subsequent layers of training activities are added, like building blocks – from simple to advanced, to help surveyors learn the concepts and skills needed to conduct a survey. Training activities and requirements are outlined in a document referred to as the "Training Plan."

d. Training Plans

QSED Training Plans serve as the roadmap for training. They outline a comprehensive series of training activities that a surveyor must successfully complete before they are allowed to independently conduct a survey. Training activities are listed in order of completion.

There is a Training Plan for each survey type. State Training Coordinators (STCs), Training Managers and Regional Training Administrators (RTAs) should utilize the Training Plans to understand the training requirements for each provider and supplier type and to assure optimal training support for each surveyor.

The Training Plan should be used to schedule, coordinate and guide a new surveyor through the series of training activities and preceptor-led on-the-job observations and mentoring. The Training Plans are available online for surveyors, STCs and RTAs. To access the plans, log onto the training portal at https://qsep.cms.gov. Then, select the link to the Training Plans

For additional information regarding the Training Plans, please see the Terms and Definitions below.

e. Training Plan -Terms and Definitions

- **Prerequisite Training (mandatory):** Prerequisite Training is the sum of all knowledge that surveyors are required to have before taking any of the Basics Training. This knowledge may be acquired through mandatory courses, required readings, orientation, on-the-job mentoring, observations, or supervised field experiences, etc.
- **Basics Training (mandatory):** Basics Training is the sum of all fundamental trainings that provide surveyors with the essential principles and processes of surveying for a specific provider or supplier type. Basics Training provides learners with a standard level of proficiency. Successful completion of all Prerequisite Training and Basics Training is required before learners are able to begin surveying independently.
- **Post-Basics Training (recommended):** The Post-Basics Training is comprised of learning opportunities designed to further enhance the skills of experienced surveyors. These trainings are available to surveyors after successful completion of all Prerequisite Training and Basics Training requirements. Post-Basics Training include Advanced Training, Refresher Training, Competency Testing, and Continuing Education.
- **Advanced Training:** Advanced Training is higher-level training aimed towards equipping experienced surveyors who have completed Basics Training and are surveying independently, with additional in-depth skills. The requirements (mandatory versus recommended) for taking Advanced Training vary from program to program.

- **Refresher Training:** Refresher Training is directed towards surveyors who have already completed all Basics Training and are proficient with the survey process. Refresher Training revisits topics such as compliance, safety, and quality procedures through simulated case-studies and scenarios. Refresher Training serves to further educate experienced surveyors, and reinforce their existing knowledge and skills on topics such as new regulations and enforcement.
- **Competency Testing:** Competency Testing assesses the proficiency, knowledge, and skills of surveyors based on specified and established performance standards. Competency Testing provides surveyors with the opportunity to demonstrate their skills through checklists and other readiness tools that are critical for superior job performance.
- **Continuing Education:** Continuing Education provides resources and activities that are designed to further enhance the skills of experienced surveyors. These trainings are intended to provide additional information related to a specific provider or supplier type.

e. Quality, Safety and Education Portal (QSEP)

QSED has released an online training delivery system called the QSEP. This user-friendly, learner-centered system is designed to empower surveyors to lead, manage and master their own training. On QSEP, Training Plans will provide learners with access to the full curriculum of training activities and guidance on the CMS survey process and knowledge of health care facility regulations.

Select this link to access the QSEP online training portal: https://qsep.cms.gov

Contact the QSEP Help Desk if you need assistance. You may reach them by phone at 1-855-791-8900 or by email at HelpDesk@QSEP.org

Please refer to the system requirements further down in this section to view the computer equipment and system requirements needed to access the federal online training available on the QSEP. The requirements must be reviewed with the IT staff to be sure that all surveyors have the proper equipment and software needed to access training.

For an introductory overview, please see the *QSEP User Training — Surveyor*[25] video

f. State Survey Agency (SA) Roles and Responsibilities

QSED works in partnership with CMS CO, CMS Locations, and SA staff to ensure a knowledgeable and skilled survey workforce throughout the United States. SA survey and certification staff play a very important role throughout the surveyor's orientation, training, and testing program. They also play an important role as participants in CMS workgroups.

SA Orientation and Field Survey Observations & Experience

Newly hired surveyors and certification staff attend a SA-led orientation and training program as the very first part of their training experience. During this time, new hires must successfully complete the CMS required prerequisites and begin on the job training and mentoring with their preceptor.

During the SA-led orientation, the new surveyor candidate pairs with an experienced preceptor/mentor to observe surveys. They observe the role of the surveyor as they mentor with their preceptor.

The new surveyor candidate continues to go on field survey observations and experiences throughout their prerequisite and basic training. At first, the new surveyor observes their preceptor as they

[25] https://qsep.cms.gov/pubs/EPlayer.aspx?cid=0CMSQSEPUT_Surveyor_ONL&sid=ad81a05f-3020-ea11-9539-0e63451df8f4&sv=0

demonstrate their skills on SA surveys and during role play. As they learn and progress, the new surveyor begins to demonstrate survey skills and abilities under the guidance of their preceptor.

The preceptor guides and mentors the new surveyor, providing feedback and reinforcement.

Eventually, the new surveyor will be able to perform the role of the surveyor independently.

The on-the-job training provided by the SA is essential for the new surveyor candidate to be able to attain the skills needed to conduct a survey. The purpose of these activities is to train the new surveyor candidate on how to apply the knowledge and demonstrate their ability to perform the skills learned in their federal and SA training.

The SA preceptor/mentor observes the surveyor candidate to assure that they have been adequately trained to conduct the CMS survey process and to make determinations about the CoPs and/or CfC of the health care facility provider or supplier being surveyed.

Participation in Workgroups

QSED continues to develop various surveyor and certification training courses. To create job-focused training, we utilize frontline expertise from SA staff to assist with content review and input. Periodically, QSED may request assistance with training development projects.

QSED may ask the SA to nominate select surveyors to participate in workgroups to test pilot training. QSED may also request participation on workgroups and committees as needed. We ask that $15,000 be placed in each SA budget for this purpose.

g. Training Schedules

Online Training

The majority of QSED surveyor training is now available online at https://qsep.cms.gov/welcome.aspx

In Person Training

All in person events are dependent on the status of the COVID-19 PHE. QSED will monitor the PHE and evaluate the possibility of holding the in-person trainings. Please see the tentative FY 21 In-Person Training Schedule below and stay tuned for updates.

Tentative FY 21 Training Schedule ***CMS Quality, Safety & Education Division***		
In-Person Training Event Dates & Locations	**Contact**	**Email**
STATE AGENCY DIRECTOR ORIENTATION COURSE (SADOC) *Monday May 17th – Tuesday May 18th 2021* *Baltimore, MD*	Program Contact	QSOG_QSED@cms.hhs.gov
	Training Coordination	QSEDLogistics@hendall.com

STATE EXECUTIVES TRAINING INSTITUTE (SETI) *Wednesday May 19th – Friday May 21st 2021* *Baltimore, MD*	Program Contact	QSOG_QSED@cms.hhs.gov
	Training Coordination	QSEDLogistics@hendall.com

Questions regarding any training content, direction, availability etc. may be directed to the QSED Mailbox at **QSOG_QSED@cms.hhs.gov.**

h. QSEP System Requirements

The following computer configuration is required to access training on QSEP. If your computer does not have the proper hardware, the training may run slowly or may not run at all. SAs and ROs must have the proper equipment and software to access and run the online training. Be sure that your computer system meets or exceeds these requirements.

Prior to running training on your computer, compare your current system configuration with the system requirements below.

Hardware Minimum Requirements

- 1.5 GHz CPU or greater with minimum of 4 GB RAM (8 GB recommended)
- Network connection (work): Ethernet, Wi-Fi
- Network connection (offsite): Fios, DSL, Cable broadband Internet (dial-up is **not** supported)
- Speakers may be required; refer to course requirements. *(Speakers are required for most Online Training)*
- Note that 3G and 4G connections are not recommended when taking tests.

Operating Systems Requirements

- Windows 8 or 10
- Mac OS X 10.7 (or later)
- Google Android 6.0 (or later)
- Apple iOS 10.0 (or later)

QSEP Officially Tested/Supported

Wherever possible, both the QSEP website (https://qsep.cms.gov) and its associated courses have been designed to run on *any* HTML5 compatible browser and on *any* platform. This includes mobile devices such as Apple iOS and Google Android compatible phones and tablets. Exceptions do exist, particularly with older course materials (created using now defunct technologies such as Adobe Flash or Windows Media Player). Where exceptions occur, QSEP will highlight the additional software requirements necessary to launch those courses. Future courses created using older technologies will be eventually be replaced with modern HTML5 versions.

The tables below highlight the platform/browser configurations tested and supported by QSEP (noted by 'X').

QSEP Tested Platforms -Microsoft Windows

Microsoft	Internet Explorer 11	Firefox	Google Chrome
Windows 8	X	X	X
Windows 10	X	X	X

QSEP Tested Platforms -Apple macOS

Apple Mac	Safari	Firefox	Google Chrome
OS X 10.7 Lion	X	X	X
OS X 10.8 Mountain Lion	X	X	X
OS X 10.9 Mavericks	X	X	X
OS X 10.10 Yosemite	X	X	X
OS X 10.11 El Capitan	X	X	X
macOS 10.12 Sierra	X	X	X
macOS 10.13 High Sierra	X	X	X
macOS 10.14 Mojave	X	X	X

Video Requirements

Videos within the online training modules are often used for scenario-based learning activities. Please see the computer requirements below:

- Windows Media Player will need to be installed and the plugin enabled on the learner's browsers for access of videos within the QSEP.
  Operating Systems Requirements
    - Windows 8, 10
    - Mac OS X 10.7 or later

  Software Requirements
    - Windows Media Player 9+

- Participants need active computer speakers with volume control.

Headset Requirements / Recommendations

Headsets are helpful to minimize distractions. Please see the recommendations below:

- If learners are in a cubicle environment, separate headsets are needed to prevent disturbance to individuals working in close proximity.
- Headsets should be capable of being plugged into the computer, to hear audio segments of online training.
- Headsets should be capable of being plugged into a phone, for participation in teleconference calls.

General Headset Specifications

Headsets vary in style. Please see the recommendations below:

- Style considerations should fit your needs: over the head, over the ear, behind the neck, wired or wireless, any adjustable style conducive to all-day wearing comfort.
- Wireless headphone devices should include rechargeable capabilities.
- Headsets require volume control, audio performance and a microphone to allow the participants to speak. Headset should not be audio only. Noise-cancelling microphones are recommended.
- Select a headset model/brand ideal for telephone intensive users: including call-center, help-desk, and customer service organizations.

Operating System and Browser Support

QSEP is a browser-based application, designed to work with the most commonly used contemporary browsers. Any hardware or operating system capable of supporting such browsers should be able to run the QSEP web site without difficulty. Specific minimum technical requirements for running QSEP are listed in the table below.

	Windows	Mac OS X	Linux
Operating Systems	Windows 8 32-bit/64-bit, Windows 8.1 32-bit/64-bit, Windows 10 32-bit/64-bit	10.6, 10.7, 10.8, 10.9, 10.10	Ubuntu 10x and 11x (Gnome), Red Hat 5, 6, Open SuSE 11.4 Fedora 15, 16 (all 32-bit)
Minimum System Requirements			
Processor	Intel Core2 Duo CPU 2.XX GHz or AMD processor (2 GB of RAM recommended)	Intel (512 MB of RAM or more recommended)	Intel or AMD x86
JavaScript	JavaScript and cookies enabled	JavaScript and cookies enabled	JavaScript and cookies enabled
Other	Active X enabled (unblocked for IE is recommended) Java 6 or later		Java 6, GNOME/KDE windowing system

	Windows	Mac OS X	Linux
Browsers			
Internet Explorer	10 (32-bit/64-bit), 11 (32-bit/64-bit)		
Firefox	Latest	Latest	Latest
Safari		5, 6, 7, 8	
Chrome	Latest 32-bit/64-bit	Latest 32-bit/64-bit	
Microsoft Edge	Version 85.0.564.51 (Official build) (64-bit)	80.0.361.109	

VPN

It is suggested that users should not access QSEP through VPN. This can block the courseware from playing.

i. Contact Information

For questions, please contact: the QSED Mailbox at QSOG_QSED@cms.hhs.gov

VIII. Hyperlinks to general resources

a. State Operations Manual

b. Policy & Memos to States and Regions

c. Administrative Information Memos to the States and Regions