DEPARTMENT OF HEALTH & HUMAN SERVICES Centers for Medicare & Medicaid Services 7500 Security Boulevard, Mail Stop C2-21-16 Baltimore, Maryland 21244-1850



Center for Clinical Standards and Quality

Admin Info: 22-03-All

DATE: January 28, 2022

TO: State Survey Agency Directors

FROM: Directors, Quality, Safety & Oversight Group (QSOG) and Survey & Operations

Group (SOG)

SUBJECT: Fiscal Year (FY) 2022 Mission & Priorities 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 2022 MPD reflects this dedication, along with our ongoing commitment to strengthen oversight, enhance enforcement, increase transparency, improve quality, and reduce burden.

FY 2022 MPD updates include:

- Updated MPD structure to include three new sections to the document: (1) new program updates since the issuance of the previous FY MPD; (2) standing information that we do not anticipate changing throughout the year; (3) listing of the priority tier structure for survey & certification activities by provider and supplier type.
- Updates to the hospice program based on the Consolidated Appropriations Act (CAA), 2021.
- Several actions for long-term care facilities that were postponed due to the COVID-19 public health emergency (PHE).
- New guidance for the backlog of End-Stage Renal Disease (ESRD) facilities surveys.

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 that 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, enforcement functions, and the Medicare funding allocation process for states, which directly affects prioritization and planning work for the required survey workload in the FY the MPD is issued. Survey activities

must be scheduled and conducted per 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 certified supplier types, accreditation and deeming 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.

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 to the MPD and/or download(s) will be made 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 relating to this memorandum, please contact your CMS Location.

Effective Date:

Immediately. Please communicate to all appropriate staff within 30 days.

/s/

Karen L. Tritz Director, Survey & Operations Group David R. Wright
Director, Quality, Safety & Oversight Group

Attachments: FY 22 MPD

Appendix 1: FY22 MPD Projected Allocations

Appendix 2: Validation Surveys

Appendix 3: Priority tier structure for survey & certification activities

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Quality Assurance for the Medicare & Medicaid Programs

FY2022 Mission & Priorities Document (MPD)

New Guidance for FY 2022

Hospice Program updates based on the Consolidated Appropriations Act 2021 (CAA 2021)

Division CC, section 407 of the CAA 2021, amended Part A of Title XVIII of Act to add a new section 1822 to the Act, and amended sections 1864(a) and 1865(b) of the Act, establishing new hospice program survey and enforcement requirements.

New provisions applying to states include:

- 1. Requirement for standard surveys at least once every 36 months;
- 2. Requiring each state to establish a toll-free hospice hotline, to collect and maintain complaint information and questions received concerning hospices in the state.
- 3. CMS posting hospice survey reports in a prominent, easily accessible, readily understandable, and searchable manner.
- 4. Providing comprehensive training for hospice surveyors;
- 5. Prohibition of conflicts of interest for hospice surveyors;
- 6. Requiring hospice surveys be conducted by a multidisciplinary team of professionals (including a registered professional nurse);
- 7. Conduct a special focus program, which includes conducting more frequent surveys of programs that are found to be noncompliant with applicable standards; and
- 8. Apply a range of enforcement remedies to hospice programs that are out of compliance with standards, including civil money penalties (CMPs).

We plan to release updated guidance on the various requirements and expectations for implementation as guidance is finalized.

COVID-19 Public Health Emergency (PHE)

As the PHE continues, SAs should be aware of COVID-19 guidance, which can be found in the Administrative and Policy memos to states and regions.

(https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo)

Resumption of Ongoing Activities and Addressing Complaint Backlogs

As a result of survey work prioritized by the PHE, many states have overdue re-certification surveys and pending complaints. SOG will continue working closely with states to discuss the state's plan to address the backlog and provide additional feedback on pending work.

Long Term Care (LTC)

CMS plans to implement several actions that were postponed due to the COVID-19 PHE. These actions include:

1. Revisions to Chapter 5 of the State Operations Manual (SOM) related to the management of facility-reported incidents and complaints, including 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.

- 2. Guidance for implementing new requirements, or revised guidance for improving the implementation of existing requirements, such as:
 - a. Nursing home staff vaccination requirements;
 - b. Phase 3 of the Requirements for Participation;
 - c. Phase 2 of the Requirements for Participation;
 - d. Addressing care for individuals with mental health needs and substance use disorder:
 - e. Implementing federal requirements related to the use of binding arbitration agreements; and
 - f. Improving the oversight of sufficient staffing.

End-Stage Renal Disease Facilities

Tier 2 Priority – flexibility: Each FY, the ESRD facility outcomes list is released, which establishes the state's workload for its tier 2 priority. The outcomes list is a confidential list for use by state agencies and CMS locations for determining annual survey priorities. It identifies the top 5% of ESRD facilities with poor clinical outcomes across defined clinical measures and States are expected to survey all identified facilities on the Outcomes List.

Due to the COVID-19 PHE and the necessary shifts in survey prioritizations, the completion of tier 2 surveys for FY2021 was delayed. As the states continue to address the backlog, some dialysis facilities that are ranked in the 5th percentile for performance on multiple, consecutive Outcomes Lists are being (or have the potential to be) surveyed more frequently than expected. CMS is providing flexibility towards completion of its surveys from the FY2022 Outcomes List by allowing deferral of certain tier 2 surveys if all of the following conditions are met:

- 1. The facility identified in the FY2022 Outcomes List was identified and surveyed based on the FY2021 Outcomes List
- 2. The prior survey was performed within the last 12 months;
- 3. The prior survey resulted in no citations or standard-only citations with an accepted plan of correction:
- 4. There are no recent complaints against the facility triaged as immediate jeopardy (IJ) or non-IJ high;
- 5. There is no other quality of care concerns.

Standing guidance

Purpose & Overview

The 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 QSOG, SOG, and the 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 FY the MPD is issued.

Regulations

The Unified Agenda of Regulatory and Deregulatory Actions reports on the actions administrative agencies plan to issue in the near and long term. For upcoming regulatory actions undertaken by both QSOG and SOG, please visit The Office of Information and Regulatory Affairs (OIRA) Unified Agenda website: https://www.reginfo.gov/public/do/eAgendaMain.

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 multitier 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 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 FY 60 days after the close of the FY. 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.

To streamline the enrollment and certification process for Medicare-certified providers/suppliers, certain certification functions performed by SOG 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 initial enrollment of Federally Qualified Health Centers (FQHCs) and will continue to occur throughout FY2022. SOG will still remain responsible for processing enforcement actions. For additional information on the transition, please see Admin Info 21-06-ALL.

Provider and Supplier Oversight

Note on Statistical Convention used throughout provider and supplier certification tier workloads:

Whenever standards are expressed in months, 0.9 of the succeeding month is included to permit the 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.

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 the 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 (MAC) approves the CMS-855. Providers/Suppliers with an accreditation option include:

- Ambulatory Surgical Centers (ASC)
- 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 (RHC)
- Psychiatric Hospitals
- End Stage Renal Disease (ESRD) Facilities

CMS-Approved Accrediting Organizations (AOs):

- Accreditation Association for Ambulatory Health Care (AAAHC) ASCs
- Accreditation Association for Ambulatory Health Care (AAAHC) ASCs
- Accreditation Commission for Healthcare, Inc. (ACHC)- ASCs, CAHs, HHAs, Hospices, ESRD facilities
- American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF)-ASCs, OPT/SLP, RHCs

- Center for Improvement in Healthcare Quality (CIHQ)- Hospitals
- Community Health Accreditation Partner (CHAP)- HHAs, Hospices
- DNV Healthcare- CAHs, Hospitals, Psychiatric Hospitals
- National Dialysis Accreditation Commission (NDAC) ESRD Facilities
- The Compliance Team (TCT) RHCs
- The Joint Commission (TJC) ASCs, CAHs, HHAs, Hospices, Hospitals, Psychiatric Hospitals

For additional information please visit: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Accrediting-Organization-Contacts-for-Prospective-Clients-.pdf

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
- Portable X-Ray Suppliers

Ambulatory Surgical Centers (ASCs)

Overview:

An ASC is a distinct entity that operates exclusively to provide surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.

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

Additional survey information:

States must continue to use the <u>Infection Control Surveyor Worksheet (Exhibit 351)</u> for each full survey of an ASC and any complaint surveys with an infection control allegation, to ensure that all applicable areas listed on the worksheet are assessed.

Beneficial 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 Medicarecertified ASCs and may be useful:

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

Priority tier structure for survey & certification activities for ASCs

		2	
Tier 1	Tier 2	Tier 3	Tier 4

Contact Information:

For questions, please contact: QSOG ASC@cms.hhs.gov

days (for deemed ASCs, within 45 days of CMS Location authorization).

Providers of Outpatient Physical Therapy (OPT) and Speech-Language Pathology (SLP) Services

Overview:

Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of OPT and SLP services are required to comply with the federal requirements outlined in the Medicare Conditions of Participation (CoP) to receive Medicare/Medicaid payment. Outpatient

rehabilitation therapy services include physical therapy (PT), including aquatic therapy, occupational therapy (OT), and SLP services.

Many rehabilitation agencies provide services from extension sites (an additional approved practice location) or in other off-premise 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).

Since these facilities have a deeming option, surveys of new OPTs are a tier 4 priority.

Priority tier structure for survey & certification activities for Providers of OPT & SLP services

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

Contact Information:

For questions, please contact: QSOG OPT@cms.hhs.gov

Comprehensive Outpatient Rehabilitation Facilities (CORFs)

Overview:

A CORF is a facility established and operated at a single fixed location exclusively to provide 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 (CoPs): Comprehensive Outpatient Rehabilitation Facilities.

S&C 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-CertificationandComplianc/CORFs.html

Additional survey information:

CORFs are surveyed every six years at a minimum.

Priority tier structure for survey & certification activities for CORFs

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

Contact Information:

For questions, please contact: QSOG CORF@cms.hhs.gov

Community Mental Health Centers (CMHCs)

Overview:

The CoPs for CMHCs can be found at 42 CFR Part 485, Subpart J. The survey interval for the CMHCs will be every five years and fall into a tier 3 workload.

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

Additional survey information:

CMS enters into agreements with CMHCs according 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 MAC.

Priority tier structure for survey & certification activities for CMHCs

Tier 1	Tier 2	Tier 3	Tier 4
Complaint	5% Targeted	5-Year Interval	Initial certification
investigations	Surveys: Each year,		of CMHCs unless
triaged as IJ	the state surveys 5%		there is verification
	of the providers in the		of access concerns.
	state (or at least one,		
	whichever isgreater),		
	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 seven		
	CMHCs.		
	Complaint		
	Investigations: non-		
	IJ high		

Contact Information:

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

End-Stage Renal Disease (ESRD) Dialysis 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 CfC 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 AO.

Continued efforts:

States are responsible for conducting initial, re-certification, complaint, and associated revisit surveys of ESRD facilities (whether independent or hospital-based).

ESRD suppliers may participate through deemed status for initial and re-certification surveys by a CMS-approved accrediting organization.

Notable aspects of the ESRD survey responsibilities include:

Relocations: 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 SOM, Chapter 2, Section 2280 for additional guidance.

Home Dialysis in Nursing Homes – onsite visits: 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.

QSOG Website for ESRD Data Reports: the state and CMS locations are responsible for assigning a Master Account Holder (MAH) to access these reports on the CMS ESRD data website at www.dialysisdata.org. The MAH may grant permission for report access to other designated users in the state or CMS location.

The states and CMS locations are expected to use the available data reports on this site as a resource during the survey process and to assist in identifying annual survey priorities. The CMS ESRD data website contains the following reports for review:

- Dialysis Facility Reports (DFR) These reports are released each FY and provide information on patient characteristics, treatment patterns, hospitalizations, mortality, and transplantation patterns for each Medicare-certified facility. The DFR characterizes selected aspects of clinical experience for an individual facility relative to other dialysis facilities in the state, ESRD Network, and across the United States. Since these data reports are useful for quality improvement and assurance activities, each state's surveying agency uses the DFR report as a resource during the S&C process to identify data-driven focus areas for review during a survey.
- Quarterly DFR Reports (Pre-survey data extract) The quarterly DFR report, also referred to as the pre-survey data extract, provides more recent data on select measures of

- the comprehensive DFR including infection, fluid management, anemia, adequacy, nutrition and mineral metabolism. These reports are released on a quarterly basis in December (Q1), March (Q2), June (Q3) and September (Q4 annual DFR).
- Outcomes List The Outcomes List is a confidential list for use by state agencies and CMS locations for determining annual survey priorities. The annual Outcomes List applies to tier 2 (targeted) survey priorities and identifies the top 5% of ESRD facilities with poor clinical outcomes across four defined clinical measures based on their potential to impact patient outcomes. The defined clinical measure include:
 - Mortality
 - Hospitalizations
 - Hospitalizations related to septicemia
 - o Long-term catheter

States are expected to survey all identified facilities on the Outcomes List unless a given facility meets the criteria for deferral specified in the "New Guidance for FY 2022." The annual process for releasing and reviewing the Outcomes List will remain the same, i.e. available on www.dialysisdata.org at or near the start of each fiscal year.

Note: The outcomes list does not apply to deemed facilities. States and CMS locations should verify if facilities on the Outcomes List are deemed before scheduling a survey for a tier 2 facility. If a facility on the Outcomes List is identified as a deemed facility by a CMS-approved AO, the facility may be removed from the state's tier 2 workload. No further action is needed.

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. 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.

Before 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 QSEP https://qsep.cms.gov/welcome.aspx
 - o ESRD Basic Core Survey Training
 - o Immediate Jeopardy (Update) Training
 - o Emergency Preparedness Basic Training
 - o 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

Priority tier structure for survey & certification activities for ESRD

Tier 1	Tier 2	Tier 3	Tier 4
Representative	Outcomes List:	3.5-Year Max	3-Year Average:
Sample Validation	100% of the ESRD	Interval (42.9	Additional surveys
Surveys: Surveys are	facilities in thestate	months): Additional	are done (beyond
conducted in a	on the Outcome List	surveys are done to	tiers 2-3) sufficient to
sample of deemed		ensure that no more	ensure that ESRD
ESRDs specified by	Investigations of	than 3.5 years elapse	facilities are surveyed
CMS (Budgeted	complaint	between surveys for	with an average
separately and	allegations triaged	any one particular	frequency of three
allocated as	as High	ESRD facility.	years or less.
supplemental funding			
during the year).		Investigations of	
		complaint	
Investigation of		allegations triaged	
complaint		as medium.	
allegationstriaged as			
IJ.		Relocations,	
		expansion of	
Initial surveys:		service(s), and/or	
States must conduct		addition of station(s)	
initial certification		requests, as needed	
surveys within 90			
days of the MAC			
approval of the CMS-			
855 unless the			
supplier has elected a			
deeming option.			

Contact Information:

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

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

Overview:

Medicare-certified RHCs are located in rural areas designated as a shortage area, are 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 shortage areas.

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.

Medicare-participating FQHCs are not subject to certification and re-certification surveys as they self-attest to compliance. However, for FQHCs, CMS investigates complaints of credible allegations of substantial violations of CMS regulatory standards 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 as detailed in Appendix G of the SOM.

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), and may be useful for RHC and FQHC surveyors, as well as Medicare-participating RHCs and FQHCs:

• RHC/FQHC Basic Training

RHC/FQHC Resource Information:

- RHC/FQHC Regulations <u>CfCs 42 CFR 49</u>
- RHC Interpretive Guidelines SOM: Appendix G

S&C activities for FQHCs and RHCs:

States will survey a 5% targeted sample of RHCs, with at least one in those states where 5% is less than one RHC. This tier 2 sample is not required for any state that has fewer than seven RHCs. States will select the sample, focusing on RHCs that have not been surveyed in more than 6 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.

RHC initial surveys are a tier 4 priority, as these facilities have two deeming options. Please see Appendix 2 for 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 FQHCs and RHCs

Tier 1	Tier 2	Tier 3	Tier 4
Complaint	5% Targeted	7-Year Interval:	6-Year Avgerage:
investigations	Surveys- RHCs:	Additional surveys	Additional surveys
prioritized IJ-	Each year, the state	are done to ensure	are done (beyond
deemed RHCs: only	surveys 5% of non-	that no more than	tiers 2-3) such that all
with CMS Location	deemed RHCs (or at	seven years elapse	non-deemed RHCs in
authorization; survey	least one, whichever	between surveys for	the state are
to be initiated within	is greater), based on	any RHC.	surveyed, on average,
two days of CMS	state judgment		every six years. (i.e.,
Location	prioritizing those		total surveys divided
authorization.	RHCs most at risk of		by total RHCs is not
	quality problems.		less than 16.7%).
Complaint	Some of the targeted		
investigations	surveys may qualify		

	1	
prioritized as IJ-	to count toward the	Initial Surveys there
FOHCs : only with	tiers 3 and 4	is a deemed status
CMS Location	priorities. States with	option for RHCs.
authorization; survey	fewer than seven	_
to be initiated within	RHC s are exempt	There is no
two days of CMS	from this	certification or re-
Location	requirement.	certification
authorization.		requirement for
	Complaint	FQHCs.
Validation surveys	investigations	
are conducted in a	prioritized as non-	
sample of deemed	IJ high: to be	
RHCs, specified by	initiated within 45	
CMS. (Budgeted	days of the	
separately and	prioritization (for	
allocated as	deemed RHCs,	
supplemental funding	within 45 days of	
during the year).	CMS Location	
	authorization).	

Contact Information:

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

Home Health Agencies (HHAs)

Overview Non-Deemed 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. Under Sections 1861(o), 1864, and 1891(c) of the Act, SAs conduct surveys of HHAs to determine whether they are complying with the CoPs.

Survey Frequency: 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 (CHOW): 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 re-certification survey with a note that this is early re-certification 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 are not automatically assigned to the new owner. An initial survey will be required and is considered a tier 4 priority. 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 HHA survey team (except as a trainee), he/she must complete the HHA Basic Surveyor Training course located in QSEP.

Overview of Deemed Home Health Agencies:

States will continue to be responsible for conducting two types of validation surveys for deemed HHAs: (1) substantial allegation complaint surveys and (2) representative sample of 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.

S&C activities for HHAs:

• 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.
- Contact information for OECs and OACs in each state is located on the following CMS website: OASIS Education Automation Coordinators

Priority tier structure for survey & certification activities for HHAs

Tier 1	Tier 2	Tier 3	Tier 4
36.9-Mo. Max.	Substantial	N/A	24.9 Mo. Avg:
Interval: No more	Allegation		Additional surveys
than 36.9 months	(Complaint)		(beyond tiers 1-3)

elapse 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 one 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 one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only when authorized by			
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 one deemed HHA is surveyed, unless that has no deemed HHAs, or unless CMS makes no assignment. An extended survey is required for any validation survey, which finds one or more conditionlevel deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) HHAs most at risk of providing poor care so all HHAs are surveyed on average or all tier 4 surveyed on average every 24 mos. (average of all tier 4 surveys 24.9 mos. to optimize the unpredictability of surveys. Surveys of HHAs de-activated (by the MAC)-for failure to bill Medicare for 12 consecutive months. Initial surveys of HHA following a CHOW where the provider agreement and billing privileges are not automatically assigned to the new owner.		Investigations	
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 one 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 one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys. JJs: Only			
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CMS during the year. At least one 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 one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	sample of deemed		Surveys of HHAs
year. At least one 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 one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	HHAs specified by		de-activated (by the
year. At least one 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 one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	CMS during the		*
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CMS makes no assignment. An extended survey is required for any validation survey, which finds one or more condition- level deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	state has no deemed		
CMS makes no assignment. An extended survey is required for any validation survey, which finds one or more condition- level deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	HHAs, or unless		Initial surveys of
assignment. An extended survey is required for any validation survey, which finds one or more condition- level deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	CMS makes no		
required for any validation survey, which finds one or more condition- level deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	assignment. An		
validation survey, which finds one or more condition- level deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	extended survey is		provider agreement
which finds one or more condition-level deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	required for any		and billing privileges
more condition- level deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	validation survey,		
level deficiencies. (Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	which finds one or		_
(Each state surveys one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	more condition-		owner.
one HHA within its standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	level deficiencies.		
standard budget allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	(Each state surveys		
allocation; additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	one HHA within its		
additional surveys are budgeted for some states via supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	standard budget		
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supplemental allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only	_		
allocation.) Substantial Allegation Validation (Complaint) Surveys - IJs: Only			
Substantial Allegation Validation (Complaint) Surveys - IJs: Only	* *		
Allegation Validation (Complaint) Surveys - IJs: Only	allocation.)		
Allegation Validation (Complaint) Surveys - IJs: Only	Substantial		
Validation (Complaint) Surveys - IJs: Only			
(Complaint) Surveys - IJs: Only	<u> </u>		
Surveys - IJs: Only			
	when authorized by		

the CMS Locations,		
complaint surveys are		
to be initiated within		
two days of CMS		
Location		
authorization.		

Contact Information:

For questions, please contact: <u>HHAsurveyprotocols@cms.hhs.gov</u>

Hospice Agencies

Overview:

The requirement to survey hospice programs every 36 months was initially established in the IMPACT ACT 2014 and has been extended recently under the CAA 2021.

When there are nursing home residents that have elected Medicare hospice services, 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. The 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 participates on a hospice survey team (except as a trainee), they must complete the Basic Hospice training course, which was updated in 2021. If a surveyor completed the training before the 2021 Basic Hospice Training was released, they are required to complete the updated training within three months of its posting.

Deemed Hospice Agencies:

States will continue to be responsible for conducting two types of validation surveys for deemed hospices: (1) substantial allegation complaint surveys and (2) 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.

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.

Priority tier structure for survey & certification activities for Hospice agencies

Tier 1	Tier 2	Tier 3	Tier 4
36-Month Max.	Complaint	N/A	Initial Surveys
Interval: No more	investigations: Non-		
than 36 months	IJ High		
between completed			
surveys for any			
particular agency.			
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 IJ –			
deemed hospices:			
only with CMS			
Location			
authorization; survey			
to be initiated within			
two days of CMS			
Location			
authorization.			

Contact Information:

For questions, please contact: QSOG Hospice@cms.hhs.gov

Hospitals 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 initial swing-bed approval, and in which case, the survey is conducted by the SA; or
- A deemed hospital or CAH is applying for an initial swing bed approval, and 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 re-certification during hospital and CAH re-certification surveys.

Appendix A (Hospital guidance) and Appendix W (CAH guidance) swing-bed sections of the SOM have been updated to align with the LTC rules and refer to Appendix PP (LTC guidance). 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 for additional details.

Emergency Medical Treatment & Labor Act (EMTALA) Investigations: Based on CMS Location review of the allegations, the complaint may be classified as IJ or non-IJ high. The timeline for investigations in hospitals and critical access hospitals (CAH) for complaints specific to EMTALA and deaths associated with restraint or seclusion must be initiated within two business days. Non-IJ high prioritization requires the survey to be initiated within 45 days.

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

Psychiatric Hospitals:

Most Medicare-certified psychiatric hospitals participate via deemed status, based on their accreditation by The Joint Commission (TJC) or DNV Healthcare (DNV). 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 Commission for Healthcare, Inc. (ACHC) or DNV, 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 ACHC or DNV 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 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.

The SAs are responsible for conducting the psychiatric surveys for the two special conditions while they conduct surveys for the regular hospital conditions in psychiatric hospitals.

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

Tier 1	Tier 2	Tier 3	Tier 4
Representative	Substantial	N/A	N/A
Sample Hospital	Allegation		
Validation Surveys:	Validation		
All states perform at	(Complaint)		

least one survey and	Investigations that	
selected states	are prioritized as	
perform additional	non-IJ high must be	
surveys of the state's	initiated within 45	
deemed hospitals,	days of CMS	
designed to validate	Location	
the surveys of AOs	authorization	
with CMS identifying		
the hospitals to be		
surveyed by each		
state. (funded via the		
state's regular		
budget) (See		
Appendix 2)		
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)		
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 AOs, or		
at least one survey in		
at least one survey in		

each state-whichever		
is greater). At least		
one 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)		
rippenaix 1)		
Substantial		
Substantial		
Allegation		
Validation		
(Complaint)		
Surveys: Only when		
authorized by the		
CMS Location. IJ		
complaints, including		
restraint/ seclusion		
death incidents, must		
be initiated or		
completed within the		
applicable SOM		
timeframe and are		
tier 1 priority.		
1 ,		
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		

curvove mov bo		
surveys may be	,	
required by the CMS		
Location after each	1	
complaint	1	
investigation that		
finds condition level	1	
non-compliance for		
deemed hospitals and		
CAHs. These are a		
tier 1 priority.	,	
tier i priority.	1	
Psychiatric Hospital		
	,	
Representative	,	
Sample Validation		
Surveys: Surveys are		
conducted in a		
sample of deemed		
psychiatric hospitals		
specified by CMS.		

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

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

Tier 1	Tier 2	Tier 3	Tier 4
Complaint surveys: 5-Ye	ear Max.	Recerts: 4-Year	3-Year Avg.:
Complaint allegations prioritized as IJs and CMS Location authorized EMTALA and restraint/ seclusion death incident surveys, initiated or completed within the applicable SOM timeframes. Som timeframes. Interthan than between any page of C and the completed within the applicable Som timeframes.	rval: No more five years elapse veen surveys for particular non- med hospital, chiatric hospital,	Recerts: 4-Year Max. Interval: No more than four years elapse between surveys for any particular non- deemed hospital or CAH. Recerts of Psych Hospitals: 3-year average recert surveys of non- accredited/non- deemed psychiatric hospitals only. New IPPS Exclusions: All new rehabilitation hospitals/units & new psychiatric units	3-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 three years (i.e., total surveys divided by total non-deemed hospitals/CAHs is not more than three years; separate calculation for hospitals and CAHs). Targeted

those most at risk	seeking exclusion	surveys may count
of providing poor	from IPPS (2),as well	toward the three year
care. Some targeted	as existing providers	avgerage.
surveys may count	newly seeking such	
toward the tier 3	exclusion. The SA	
and 4 priorities.	does not need to	
Targeted sample	conduct an on-site	
requirements do	survey for	
not apply to States	verification of the	
with fewer than	exclusion	
seven non-deemed	requirements but	
hospitals,	instead may process	
psychiatric	an attestation	
hospitals, or CAHs.		

For questions, please contact: QSOG Hospital@cms.hhs.gov

Contact Information

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

Critical Access Hospitals (CAHs) Overview

To receive Medicare/ Medicaid payment, CAHs must comply with the federal requirements set forth in the Medicare CoPs. The goal of a CAH survey is to determine if the CAH complies with the CoP set forth at 42 CFR Part 485 Subpart F. The most current CAH interpretive guidance, in the SOM Appendix W.

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. See SOM Chapter 2 - The Certification Process for additional information.

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 after that may seek conversion to CAH status.

- Therefore, requests from a non-deemed hospital to be certified as a CAH are not treated as initial surveys but as conversions and maybe surveyed as a tier 2, 3, or 4 priority.
- AOs with a CMS-approved CAH program can conduct a CAH conversion survey.

Annually, the CAH Distance Analysis Committee, comprised of staff from QSOG and SOG, will assess compliance with the location and distance requirements for CAHs before the due date of their triannual (every three years) re-certification or reaccreditation survey. The CMS locations will be responsible for completing a comprehensive assessment of any CAH within its jurisdiction that seeks to add an off-campus location or any hospital seeking conversion to CAH status. All assessments will evaluate the distance and location requirements of the main location

and all provider-based off-site locations per memos <u>QSO Memo 16-08-CAH</u> and <u>QSO Memo 19-16-CAH</u>.

The CAH checklist has been updated to assist with documenting the results of the assessment. When you have completed all the steps of this SOP, ensure all results are recorded on the CAH checklist.

When the review demonstrates compliance with the location and distance requirements, the CAH Committee will send the completed checklists to the CMS Location overseeing the CAH to file the completed checklist in the CAH's file.

For issues identified during re-certification reviews, send the CAH checklist and description of the issue to the larger CAH Committee to discuss before escalating the issue to Senior Leadership.

For issues identified during CAH conversions or adding provider-based location reviews send a copy of the CAH checklist and description of the issues to your manager and the CMS SOG Division Director to address with the SOG Group Director/Deputy.

CAHs Adding Provider-based Locations

The MAC reviews the CAH's provider-enrollment application (Form CMS-855) for the addition of a provider-based location. Once completed, the MAC forwards the form and any submitted documentation to their CMS Location 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 their application (Form CMS-855), the CMS Location will request that information from the CAH during their distance review.

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

• The MAC takes no 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 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 altogether.
 - 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 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 another Form CMS-855 to the MAC 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 notifies the MAC of its review that the CAH complies 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 QSOG and CMS Location 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, and the SA.
- The CMS Location notifies the AO (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 guidance.

Additional 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. Therefore, requests from a non-deemed hospital to be certified as a CAH are not treated as initial surveys but as conversions and maybe surveyed as tier 2, 3, or 4 priorities, at the state's 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, CAHs 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 3 priority.

- AOs with a CMS-approved CAH programs are able to conduct a CAH conversion survey. There are three AOs with approved CAH accreditation programs: ACHC, DNV, 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 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.
- Swing-bed services will be covered under the Hospitals section. See <u>QSO Memo 18-26-Hospitals/CAH</u> for additional swing bed guidance.

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

		& CAHs (Deemed)	
Tier 1	Tier 2	Tier 3	Tier 4
Representative	Substantial	N/A	N/A
Sample Hospital	Allegation		
Validation Surveys:	Validation		
All states perform at	(Complaint)		
least one survey and	Investigations that		
selected states	are prioritized as		
perform additional	non-IJ high must be		
surveys of the state's	initiated within 45		
deemed hospitals,	days of CMS		
designed to validate	Location		
the surveys of AOs	authorization		
with CMS identifying			
the hospitals to be			
surveyed by each			
state. (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)	,	
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 AOs, or		
at least one survey in		
each state-whichever		
is greater). At least		
one 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, must		
be initiated or		
completed within the		
applicable SOM		
applicable SOM		

tier 1 priority. EMTALA Complaint Surveys: Only when authorized by the CMS Location. All EMTALA complaints surveys authorized are prioritized as IIs 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	timeframe and are	1	
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			
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Representative Sample Validation Surveys: Surveys are conducted in a sample of deemed			
Representative Sample Validation Surveys: Surveys are conducted in a sample of deemed	Psychiatric Hospital		
Sample Validation Surveys: Surveys are conducted in a sample of deemed	1 2		
Surveys: Surveys are conducted in a sample of deemed			
conducted in a sample of deemed			
sample of deemed			
psychiatric hospitals	psychiatric hospitals		
specified by CMS.			

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

Tier 1	Tier 2	Tier 3	Tier 4
Complaint surveys:	5-Year Max.	Recerts: 4-Year	3-Year Avg.:
Complaint allegations	Interval: No more	Max. Interval: No	Additional surveys
prioritized as IJs and	than five years elapse	more than four years	are done (beyond

CMS Location authorized EMTALA and restraint/ seclusion death incident surveys, initiated or completed within the applicable SOM timeframes. between surveys for any particular nondeemed hospital, psychiatric hospital, or CAH.

5% Targeted Sample: States survey at least one, but not less than 5% of the nondeemed hospitals, 5% of the nondeemed 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 count toward the tier 3 and 4 priorities. Targeted sample requirements do not apply to States with fewer than seven non-deemed hospitals, psychiatric hospitals, or CAHs.

elapse between surveys for any particular nondeemed hospital or CAH.

Recerts of Psych Hospitals: 3-year average recert surveys of nonaccredited/nondeemed 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

tiers 2 and 3), based on state judgment regarding the nondeemed 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 three years (i.e., total surveys divided by total nondeemed hospitals/CAHs is not more than three years; separate calculation for hospitals and CAHs). Targeted surveys may count toward the three year avgerage.

Contact Information

For questions, please contact: QSOG Hospital@cms.hhs.gov

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 <u>S&C: 12-29-ALL</u>. The comprehensive state performance standards (SPSS) monitor the 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 re-certification 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 online basic 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 on record and paperwork review and increase surveyor observations and interactions with the residents and staff.

Additional information can be found on the ICF/IID portion of the CMS website.

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

Tier 1	Tier 2	Tier 3	Tier 4
15.9 Mo. Max.	Complaint	Complaint	Initial Surveys
Interval:No more	investigations	investigations	
than 15.9 months	triaged as Non-IJ	triaged as Non-IJ	Complaint
elapse between	high	medium	investigations
completed surveys			triaged as Non-IJ
for any particular			low
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.			

Contact Information

For questions, please contact: QSOG ICFIID@cms.hhs.gov

Long Term Care (LTC)

Ongoing Efforts

• 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% 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% of these surveys (or 5% of all surveys) must be conducted on weekends in facilities with potential staffing issues.
- 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 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;
 - o Participating in CMS-sponsored workgroups, meetings, and conferences;
 - Conducting at least two structured provider training courses within the FY, 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
 - o 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 to fund activities attributable to Medicaid facilities or dually-certified facilities.
- Focused Infection Control Surveys: States must perform annual Focused Infection Control surveys of 20% of nursing homes based on state discretion or additional data that identifies facility and community risk, such as facilities in counties with high rates of COVID-19 community transmission, facilities with multiple weeks of reporting COVID-19 cases, Special Focus Facilities (SFFs), facilities identified as candidates for the SFF program, or facilities with allegations or complaints which pose a risk for harm or Immediate Jeopardy to the health or safety of residents.
- 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 SOM for additional
 requirements.
- Review of Requests for Waiver of Nurse Aide Training Program two-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 memo for additional clarification.

- Enforcement and Civil Money Penalty (CMP) tool: CMS will continue to work on enforcement policies to support compliance. States are required to transfer all cases that warrant enforcement to the CMS Location.
- State reinvestment of CMP funds: 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). 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.
- <u>Emergency preparedness surveys</u>: Please refer to the Emergency Preparedness website for additional information for these requirements and surveys.

Standard Health Survey Process

- All states must use the long-term care survey process (LTCSP) to assess compliance with the Requirements for Participation (RfP). CMS will continue to make software and guidance updates to existing and new regulations and will update the LTCSP Procedures Guide and Training documents accordingly.
 - o Resources for all of these changes can be found on QSEP at https://qsep.cms.gov/ and at: Guidance to Laws & Regulations: Nursing Homes

• Other Areas of Importance

- o National Partnership to Improve Dementia Care: CMS has partnered with federal and state agencies, nursing homes, other providers, advocacy groups, and caregivers to improve comprehensive dementia care. CMS and its partners are committed to finding new ways to implement practices that enhance the quality of life for nursing home residents with dementia through promoting goal-directed, person-centered care for every nursing home resident. CMS continues to focus on reducing the use of antipsychotics and enhancing the use of non-pharmacologic approaches and person-centered dementia care practices in all nursing homes when their use is not clinically indicated. Also, we plan to evaluate actions to address concerns about facilities using an inappropriate process to diagnose residents with schizophrenia to improve their quality measures artificially. We will communicate any new updates or initiatives as we progress.
- O 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 resident's health and safety at risk. CMS requires states to transfer any case that involves non-compliance related to involuntary discharge to their CMS Location. CMS Locations will evaluate the non-compliance and impose the appropriate enforcement remedy.

Priority tier structure for survey & certification activities for LTC

Tier 1	Tier 2	Tier 3	Tier 4
15.9-Month Max.	"Off-Hours"	Initial Surveys of	Complaint
Interval: No more	Surveys: States are	Nursing Homes that	investigations
than 15.9 months	required to conduct at	are seeking	

elapse between	least 10% of the	Medicaid-only	triaged as Non-IJ
completed surveys	standard health	funding —funded only	low
for any particular	surveys on the	by Medicaid (not	10 11
nursing home.	weekend or before	Medicare) and	
naising nome.	8:00 a.m. or after	surveyed at state	
12.9-Mo. Avg: All	6:00 p.m. (i.e., "off-	priority.	
nursing homes in the	hours). States shall	priority.	
state are surveyed, on	conduct at least 50%	Initial Surveys of	
average, once per	of their required off-	Nursing Homes	
year. The statewide	hours surveys on	seeking dual	
average interval	weekends using the	Medicare/Medicaid	
between consecutive	list of facilities with	certification*	
		ceruncation.	
standard surveys	potential staffing	Compleint	
must be 12.9 months	issues provided by	Complaint	
or less.	CMS.	investigations	
		triaged as Non-IJ	
Complaint	Complaint	medium	
investigations	investigations		
triaged as IJ	triaged as Non-IJ		
	high		

^{*}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: <u>DNH TriageTeam@cms.hhs.gov</u>

Portable X-Ray (PXR) Suppliers

Statutory Authority

The statutory authority for coverage of suppliers of portable x-ray services is found in §1861(s)(3) of the Act. The regulations are found in 42 CFR 486, Subparts A-C. The SOM Appendix D contains surveyor and interpretive guidelines.

Diagnostic x-ray tests (including tests furnished in a place of residence used as the patient's home) must be under the supervision of a physician. The "residence used as the patient's home" can include a SNF or hospital that does not provide x-ray services for its patients and arranges for these services through a portable x-ray supplier, such as a mobile unit. However, to be certified as a portable x-ray supplier, the mobile unit can neither be fixed at any one location nor permanently located in a SNF or a hospital. (SOM section 2420).

Location of Portable (PXR) Services

Despite the mobility of the services, the base office address of the supplier must be identified as the supplier, and the supplier must be approved in each state in which its operation is based. A post office box number does not suffice.

Portable x-ray suppliers operating across state lines may or may not maintain separate offices in multiple states. Those that operate in states other than where they are based must meet each state's state and local laws in which they operate. In such instances, the certifying SA must check whether the other state permits such operation by reciprocal state agreements. Note on the survey report whether the other state has such a requirement, and if so, whether the specific supplier is permitted to operate in the other state. (SOM Section 2422).

Priority tier structure for survey & certification activities for PXR

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

Contact Information

For questions, please contact: CMSQSOG PXR@cms.hhs.gov

Psychiatric Residential Treatment Facilities (PRTFs)

Overview:

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 CoP for the use of restraint and seclusion that PRTFs must meet to continue to provide Medicaid inpatient psychiatric services to patients under 21.

Survey activity information:

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 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 and https://www.cms.gov/Regulations-and-Guidance/Manuals/Downloads/som107c02.pdf

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

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

Contact Information

For questions, please contact: QSOG PRTF@cms.hhs.gov

Religious Nonmedical Health Care Institutions (RNHCIs)

No new changes or efforts. If any changes arise, CMS will send updates as appropriate.

Contact Information

For questions, please contact: Survey Operations Group- Northeast at

CMSBOSTONLTC@cms.hhs.gov

Transplant Program

The transplant program re-certification survey interval has been changed to a maximum of five years to be consistent with the hospital survey intervals.

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 organ transplant programs. Initial transplant reports are available for each transplant program type to determine compliance with these requirements.

State agencies should email the transplant mailbox at <u>QSOG_TransplantTeam@cms.hhs.gov</u> 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.

Surveyor Qualifications

Before any state or federal surveyor may serve on a survey team (except as a trainee) for a transplant program survey, they must complete the Transplant Basic Surveyor Training course located in QSEP.

Priority tier structure for survey & certification activities for Transplant Programs

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

Contact Information

For questions, please contact: QSOG TransplantTeam@cms.hhs.gov

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 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. 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.

CMS will not manage the acquisition of the NFPA CFI-1 certification for SA LSC surveyor candidates. The SAs are responsible for addressing all matters necessary to obtain CFI-1 certification 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/Certified-Fire-Inspector-I

Leadership Training:

SA Directors and Deputy Directors must 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.

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

It is essential that accurate (e.g., survey coding) and complete survey data is 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, including completing the CMS-670 per system requirements and CMS SOM Chapter 2, Section 2705, and evaluating their surveyor times.

Quality Improvement Initiative

Quality Improvement Organizations (QIOs), ESRD Networks, and SA partnerships are critical to improving 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 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. 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 required 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;
 - o Make sure that surveyors follow the survey protocols and processes;
 - o 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 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
 - o Ensure that the RAI coordinator provides support and technical assistance for nursing homes in the coding of the MDS.
 - o 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 longstay 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 S&C 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 federal requirements. This includes assuring:

- 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 is 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 the 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 the implementation of this regulation.

Home Health & Hospice Toll-Free Hotline and Investigative Unit

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

States must ensure that complaints from the hotline are effectively captured in the appropriate national database system.

RAI/MDS

All certified nursing homes and swing bed hospitals are required to encode and transmit MDS records to CMS following CMS established record specifications and timeframes. 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 FY. 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 virtual 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;
 - o 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 of the coding of resident assessments; and the transmission of
 MDS data;
- The collection and housing of MDS data so 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;
- Complete semi-annual reporting of the CMS MDS training worksheet in the appropriate system to report the educational offerings that were conducted in the state during the year.
- Providing comprehensive education to CMS Location, SA RAI, and nursing home field-surveyor preceptors (RAI coordinators' conference and MDS 3.0 educational offerings) 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 CMS Location 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.

States are responsible for assuring their SA staff are trained in the use of the RAI process, including the MDS 3.0 and changes to the SOM, survey reports, and processes as a result of those changes. Each SA will be responsible for its RAI and Automation Coordinators and a nursing home field-surveyor preceptor, participating in the RAI Coordinators' Conference and MDS 3.0 educational offerings in the FY, which may also include a series of webinars. States are also responsible for ensuring that their RAI Coordinator(s) and S&C staff members collaborate 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)

Per CMS-established record specifications and time frames, all certified HHAs are required to encode and transmit OASIS records for Medicare and Medicaid beneficiaries to the national OASIS database system. CMS expects states to continue to play a key role in providing educational and technical resources 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:

- Each State has a designated OASIS OEC with the responsibility to ensure that all home care providers in the State have access to:
 - o Training on the OASIS data
 - Training and technical support in integrating the OASIS items in the agency's record keeping system
- Each State has a designated OASIS OAC with the responsibility to ensure that all home care providers in the State have access to:
 - o Training on the electronic submission of OASIS data
 - o Training on correction of errors to OASIS data
 - o Support in answering questions on the technical aspects of OASIS

The Home Health Quality Help Desk provides guidance on OASIS coding and documentation of OASIS items. OACs & OECs may refer unresolved issues to the Home Health Quality Reporting Program mailbox: homehealthqualityquestions@cms.hhs.gov.

Quality Improvement and Evaluation System (QIES) Automation Related Activities

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 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 the right 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 for MDS, SB-MDS, and OASIS encoding and transmission. However, state personnel 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 MDS and OASIS Automation Project Plans submitted with its prior-year budget requests. States should provide 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 S&C 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 S&C 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 S&C Program will be 75%. Budget estimates should be prepared and submitted as part of each state's S&C 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 S&C 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 S&C 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% 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 share in the MDS and OASIS automation costs.

The Quality Improvement and Evaluation System (QIES)

CMS goals for the standardized MDS, SB-MDS, and OASIS systems 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, SB-MDS, and OASIS 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 can 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*	FT	All Provider types/State
	E	(Excluding CLIA)
1	4	<600
2	4.5	600-1500
3	5	>1500

^{*}These ranks may be adjusted upward if the CMS Location believes the volume of a state's complaints warrants 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 amongMDS/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)
 - o To improve survey efficiency and time associated with accessing information, states should ensure their survey staff have access to high-speed internet.
- Information Systems Hardware
 - O 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 SA 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 SA 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 SA 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 before the scheduled move date.

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

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), the state submits a plan and budget request to support upgrading 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 the 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.

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 ten 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.

- Laptops: Recommended field system is any Windows computer designed for light-weight portability and provides both a keyboard option and an option to operate the device as a flat tablet. Any selected surveyor computer must also meet the required technical specification provided.
- 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, including for home-based systems. For additional information, please see CMS encryption policy.

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.

Minimum and Recommended Client Requirements: EXISTING or NEW EQUIPMENT			
Component	Minimum	Minimum or Higher Required for LTC SurveyProcess 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 BusPort	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	Wired for network connectivity; and	Wired for network connectivity; and
(See CMS ARS security guidelinesfor acceptablewireless configurations)	Wireless network cards mustsupport WPA-2 level encryption	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 SurveyProcess 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 v11 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.

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

Emergency Preparedness

SAs operate in the larger context of state emergency preparedness and often play important roles within a State Incident Command System (ICS) that extends beyond federal survey and certification functions. In such cases, states have cost accounting systems in place to properly allocate expenses 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 effectively conduct federal quality assurance and, as such, are appropriately 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. We recognize some states may already have well-developed systems that exceed the elements described here. However, we appreciate that for many states, enhanced IT reporting capabilities require additional time to implement.

- 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:
 - Essential S&C business functions, including:
 - o Provision of prompt responses to complaints regarding patients/residents who are in immediate jeopardy.
 - O 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 to ensure the health and safety of patients and residents.
 - o Conducting timely surveys or re-surveys in the aftermath of a disaster.
 - Identification of strategies to ensure maintenance and protection of S&C critical data.
 - 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
 - *Point of contact*: A state S&C emergency point of contact (and back-up) is available 24/7 to the CMS Location when the state declares a widespread disaster. The contact:
 - o Coordinates state S&C activities with CMS;
 - o Addresses questions and concerns regarding S&C essential functions;
 - o 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 assigned to communicate with CMS and provide data for S&C functions.

- Policy communications: The SA maintains the 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 assigned to perform these functions.
- Information and status reports: The SA or the State ICS maintains capability and operational protocols to provide the CMS Location with (i) state policy actions (such as a Governor's emergency declarations or waiver of licensure requirements) and (ii) 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 Address (Street, City, ZIP Code, County) Current emergency contact name Contact's telephone number and alternate number (e.g., cell phone) Contact's email address 	 For-profit/ or not-for-profit agency, or government agency status Provider status (evacuated, closed, damaged) Provider census Available beds 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 	 Estimated date for restored operations Source of information Date of the status information

Recovery Functions

The SA and the CMS Locations will determine recovery functions on a case-by-case basis between. In the context of S&C, recovery functions represent those activities that are required to ensure that a provider has reestablished the environment and systems of care necessary to comply with federal certification requirements.

Funding

We believe that the types of actions that we specify 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. Therefore, we encourage SAs to seek other available sources of emergency services funding or grants to promote emergency preparedness coordination wherever possible and 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 financial 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 of this is pre-survey site visits in the aftermath of a disaster, before 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 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 will be considered 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.

Web-based Platform for Section 1135 Waivers during Emergencies

When the President declares a disaster or emergency under the Stafford Act or National
Emergencies Act, and the HHS Secretary declares a Public Health Emergency (PHE) under
Section 319 of the Public Health Service Act, the Secretary is authorized to take certain actions
in addition to his/her regular authorities. For example, under Section 1135 of the Social Security
Act, the Secretary may temporarily waive or modify certain Medicare, Medicaid, and Children's
Health Insurance Program (CHIP) requirements. During a PHE, such as the COVID-19
pandemic, CMS must be able to both answer PHE-related inquiries and respond to waiver
requests. This must be done in a timely manner to respond quickly to unfolding events.

In 2021, CMS created an automated 1135 process with a publicly accessible web form. The form offers standardized, user-friendly submissions by requesters. Effective January 11, 2021, all Section 1135 waiver requests and/or inquiries should be directed to the CMS 1135 web portal at: https://cmsqualitysupport.servicenowservices.com/cms_1135 for processing. In addition, training on this new web portal can be found at the CMS YouTube 1135 Waiver and Public Health Emergency (PHE) Inquiry Web Training.

Note: Submitters should <u>not</u> send new 1135 waiver requests to local CMS Location email addresses or the new PHE-related inquiries to the COVID-19@cms.hhs.gov address.

Relationship to SPSS

If a significant emergency occurs in a state that disrupts normal s&c activity and that is well outside the level that can typically be expected in the state, CMS will take such circumstances into account 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 S&C 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. 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 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 is an important aspect of such a system. Concerning the 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.

Providers/Suppliers: Tier 1-3 performance is measured by SPSS			
Statutory Providers	Other Providers		
Nursing homes	Hospitals (all types)		
HHAs	RHCs		
Hospices	ESRD facilities		
Validations- of all deemed providers/suppliers	ASCs		
ICF/IIDs	OPTs (Rehabilitation Agencies)		
	CORFS		

States must track their tier workload on a quarterly and annual basis. During 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.

All of the following are considered tier 1 S&C activities of Core Infrastructure:

- Timely 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 and hospice hotline;
- Performance measurement activities;
- Implement & promote the fulfillment of CMS Government Performance and Results Act (GPRA) goals and quality initiatives as needed;
- Training of S&C staff, including transcript & qualifications maintenance; and
- Emergency preparedness essential functions.

Contact Information

For questions, please contact the appropriate program area:

QSOG ASC@cms.hhs.gov

QSOG CORF@cms.hhs.gov

HHAsurveyprotocols@cms.hhs.gov

HHAsurveyprotocols@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

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	Relocations of the	Initial certification	Initial certifications
of the ESRD	parent or main	of the following:	of all provider/
Facilities	location of existing	 Transplant 	supplier types that
	non-deemed	programs	have a deemed
	providers or	SNF/NFs	accreditation option
	suppliers.		(with the exception
		Relocations of non-	of ESRD): hospitals,
	Relocations of any	deemed branches or	home health, new
	provider/supplier	off- site locations.	home health
	displaced during a	<i>Note</i> : Conversion of a	branches, hospice,
	public health	non-deemed hospital	expansion of
	emergency declared	to a CAH, or a non-	inpatient hospice for
	by HHS.	deemed CAH back to	a currently certified
		a hospital is a	hospice, ambulatory
		conversion, not an	surgical centers,
		initial certification	outpatient physical

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 service in an existing deemed or non-deemed hospital or CAH is a tier 4 priority. therapy, and rural health clinics.

While CAHs may also be deemed, these are conversions, not initial certifications; however, deemed CAHs are 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 multiple hospice locations may warrant a survey. These surveys should be scheduled consistent with the tier structure as they are often resource intensive.

All other newlyapplying 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.

Priority tier structure for survey & certification activities for Complaint Investigations

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

Budget Formulation Guidelines

CMS is instituting a modified budget process for FY 2022, and as such, this information has been previously disseminated to SAs via the CMS Location offices. This process requires states to evaluate

and justify planned Medicare survey workload and budgets, consistent with MPD requirements, at two separate funding levels: a flat-lined funding level (FY 2021), and a reasonable State-determined funding level. CMS further asks states to evaluate and identify funding requirements for remaining CARES Act work in FY 2022 and FY 2023, in light of planned Medicare work. Annual funding allocations will be finalized once the FY 2022 appropriations are enacted, and further guidance will be provided.

Due Dates:

State materials due to CMS Locations: 10/22/2021; CMS Location recommendations to HQ: 11/5/2021; CMS report out to CCSQ Leadership: 11/19/2021.

Budget Plan for FY22:

Medicare Survey and Certification

CMS requests states carefully review their ongoing Medicare workload and submit an initial budget plan and limited justification materials for FY 2022 at two separate funding levels:

- 1. Current flat-lined funding levels; and
- 2. State-determined requirements.

State funding guidelines at the flat-lined level are provided in the attached materials; There are no guidelines for the state-determined level, as CMS requests each state provide its individual need. States shall briefly describe the funding level, key workload, and tier-level completion in accordance with current MPD requirements at both funding levels, as provided in the attachments. In turn, each CMS Location will review and submit their recommendation to CMS Central Office for final disposition. CMS will finalize state allocations and request routine budget materials (CMS-435's, 434's, 1465's, etc.) when final appropriations have been enacted.

Under the flat-lined scenario, States shall consider utilizing available Medicare fund sources such as Program Management, IMPACT Act (Hospice), and the newly enacted CAA 2021. Please note, Hospice survey requirements will be funded by the IMPACT Act and the CAA.

Under the state-determined funding level, states shall detail the additional work, including MPD tier completion and funding requirements that each state could realistically and feasibly accomplish given state-specific circumstances such as staffing constraints, timing, pandemic-related restrictions, etc. In short, CMS is asking each state to identify what it can reasonably accomplish, given current conditions in the field. Points to consider include:

- 1. Availability of survey staff to complete more surveys;
- 2. Authority to hire more staff;
- 3. Survey backlog;
- 4. State Medicaid funding match availability (applicable facility types).

The information requested in this portion of the budget call will enable CMS to better allocate funds to the individual states in the event additional funds are appropriated. However, it should be noted that if the CMS Location staff has additional procedures/forms in place for the budget process, this request does not preclude the state from providing that information as well.

CMS Locations complete review of the states submissions and offer recommendations, by state, to the CMS Central Office by the date listed above (<u>Bary.Slovikosky@cms.hhs.gov</u>).

IMPACT Act

Continuing through FY 2025, the amount of annual IMPACT funding available has been reduced from the prior year's allocations. Starting in FY 2022, funds to cover the shortfall in IMPACT funds will come from the CAA 2021 fund source. In execution, each state will receive funds from only one fund source, either the IMPACT Act or CAA 2021. The final IMPACT funding allocations will be made available once all of the state requests have been received for the year (December 17, 2021). All IMPACT funds should be reported separately on the mini CMS 435 Hospice form. IMPACT funding amounts should not be included on the main CMS 435. 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 staff.

CAA 2021

The FY 2021 appropriations bill provided additional funds for Hospice survey work, beginning in FY 2022. This funding will be utilized and made available in conjunction with the IMPACT funding to fully fund all hospice survey work. To ensure that there is no confusion among multiple funding sources, each state will receive funds from only one of the two fund sources, the CAA funds or IMPACT Act, not both. States will be informed which type of funding is provided. All CAA funds should be reported separately on the mini CMS 435 CAA form. However, like IMPACT funds, CAA funding amounts should not be included on the main CMS 435. 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 staff. The CAA 2021 provides funds for additional hospice-related work, including a Special Focus Facility program. Rough estimates for this activity should be included in your budget requests. Further details on this program will be provided by CMS QSOG/SOG program staff.

CARES Act

In conjunction with the budget plan for the Medicare Survey and Certification program funding above, CMS requests a budget plan for the remaining CARES Act funding needs for each State in both FY 2022 and FY 2023. Each state is asked to provide a brief description of the funding level and key workload each state expects to complete per year in FY's 2022 and 2023, as indicated in the attachment. At this time, when considering the effects of the regular Program Management appropriation on your CARES Act needs, please utilize the flat-lined funding scenario described above. CMS will continue to monitor and reevaluate future CARES Act needs if additional discretionary funds are enacted.

At this time, if a state has identified CARES Act funding expected to remain unused by the end of FY 2023, we ask the state to report the amount of excess allocation, the timeframe in which the excess can be redistributed, along with an affirmative statement from the state that the funds will not be needed and can be reallocated. Please respond affirmatively if the state expects to have no excess funding.

Continued guidelines from previous FYs

Title XVIII Budget Closeouts

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 intended to add existing work to SAs; in fact, this focus should help states close out their financial books sooner rather than sometimes waiting for five 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, statutes, 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 Central Office 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 Central Office will work with states on a case-by-case basis if there are reasons that they are unable to meet the guidelines noted above.

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 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 S&C 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. State

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 CMS-435 form (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 Expenditures for the Medical Assistance Program (form CMS-64). There are no provisions for covering these expenses in the Medicaid S&C budgets.

- Costs incurred in joint Titles XVIII/XIX facilities for NAR/NATCEP will be charged and reimbursed 50% by Medicare and 50% 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 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 expenditures for the FY (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-435 COVID-19 (pending funds availability) Captures all CARES Act projected spread across the appropriate line items;
- 5. CMS-434 Planned Workload Report;
- 6. CMS-1465A Budget List of Positions;
- 7. CMS-1466 Schedule for Equipment purchases;
- 8. Budget narrative with work plan and line by line justification;
- 9. 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;

10. Most recent Indirect Cost Agreement.

CMS Budget Analysis and Adjustment

CMS' Central Office will continue to partner with CMS Locations to review and agree upon a final budget amount for FY22 for each state once Congress has finalized a budget. The funding available to states will be allocated based on several factors that are considered such as:

- Historical Spending;
- Workload Requirements;
- State Hiring Challenges.

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

Contact Information

For questions, please contact: Your CMS Location budget staff and or Bary Slovikosky (Bary.Slovikosky@cms.hhs.gov)

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 as a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purposes of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

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

AOs with CMS-Approved Programs

Currently there are seven AOs with CMS-approved programs:

- American Association for Laboratory Accreditation (A2LA)
- American Association of Blood Banks (AABB)
- American Society for Histocompatibility & Immunogenetics (ASHI)
- College of American Pathologists (CAP)
- COLA, Inc. (COLA)
- Accreditation Commission for Health Care (ACHC)
- 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 specific 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
- SOM Appendix C: Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services

Priority QSOG Activities for Laboratories

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

- Complaint
- Validation
- Recertification
- Initial

Contact Information

For questions, please contact: <u>LabExcellence@cms.hhs.gov</u>

Quality, Safety & Education Division (QSED)

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 the Department of Health and Human Services (HHS).

Statutory Authority

The Social Security 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 [CoPs] of providers", as well as the 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).

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 survey per 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:

- ASCs
- CAHs
- CLIA
- CMHCs
- ESRDs
- HHAs
- Hospices
- Hospitals, including:
- EMTALA
- Psych Hospitals
- Transplant
- ICF/IIDs
- LSC
- LTC
- OPT/OSP
- PRTFs
- RHCs & FQHCs
- OPOs

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."

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 each provider and supplier type's training requirements and 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://gsep.cms.gov and then, select the link to the Training Plans.

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

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 can 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.

Quality, Safety and Education Portal (QSEP)

QSEP is a user-friendly, learner-centered system designed to empower surveyors to lead, manage, and master their 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.

QSEP online training portal: https://qsep.cms.gov

Should you need assistance, please contact the QSEP Help Desk by phone at 1-855-791-8900 or 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 ensure that all surveyors have the proper equipment and software needed to access training.

For an introductory overview, please see the QSEP User Training — Surveyor25 video

SA Roles and Responsibilities

QSED works in partnership with CMS Central Office, CMS Locations, and SA staff to ensure a knowledgeable and skilled survey workforce throughout the United States. SA survey and certification staff play a vital 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

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

The new surveyor candidate pairs with an experienced preceptor/mentor during the SA-led orientation to observe surveys. They observe the role of the surveyor as their preceptor mentors them. The new surveyor candidate continues to attend field survey observations and experiences throughout their prerequisite and basic training. At first, the new surveyor observes their preceptor as they 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 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 in workgroups and committees as needed. We ask that \$15,000 be placed in each SA budget for this purpose.

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 will be communicated as appropriate.

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

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 CMS Locations 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.

Before 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 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').

OSEP Tested Platforms - Microsoft Windows

Microsoft	Internet Explorer 11	Firefox	GoogleChrome
Windows 8	X	X	X
Windows 10	X	X	X

QSEP Tested Platforms -Apple macOS

			Google
Apple Mac	Safari	Firefox	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
 - o Windows 8, 10
 - o Mac OS X 10.7 or later Software Requirements
 - O 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 website 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-	10.6, 10.7, 10.8, 10.9, 10.10	Ubuntu 10x and 11x (Gnome), Red Hat 5, 6,
	bit/64-bit, Windows	10.10	Open SuSE 11.4
	1032-bit/64-bit		Fedora 15, 16 (all 32-
			bit)
	Minimum Syste	m Requirements	_
Processor	Intel Core2 Duo CPU 2.XX GHz or AMD processor (2 GB of RAM recommended)	Intel (512 MB of RAMor more recommended)	Intel or AMD x86
JavaScript	JavaScript and cookiesenabled	JavaScript and cookiesenabled	JavaScript and cookiesenabled
Other	Active X enabled (unblocked for IE is recommended) Java 6 or later		Java 6, GNOME/KDE windowing system
	Brov	vsers	
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.

Contact Information

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

General resources

State Operations Manual

Policy & Memos to States and Regions

Administrative Information Memos to the States and Regions