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: 22-02-ALL
REVISED 05.19.2022
REVISED 11.07.2022

DATE: December 22, 2021

TO: State Survey Agency Directors

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

SUBJECT: Transitioning Certification Functions for Changes of Ownership, Administrative Changes, and Initial Enrollment Performed by the SOG Locations

******Revised to Transition Several Providers and Suppliers and Provide Additional Guidance and Updates to the Standard Operating Procedures******

Memorandum Summary

- The Centers for Medicare & Medicaid Services (CMS) has been transitioning certain certification enrollment functions performed by the CMS SOG Locations (formerly CMS Regional Offices) to CMS's Center for Program Integrity (CPI) and its Provider Enrollment Oversight Group (PEOG) and to the Medicare Administrative Contractors (MACs).
- CMS has already streamlined certain certification work, such as voluntary termination (July 27, 2020), Federally Qualified Health Centers (FQHCs) enrollment (March 22, 2021), and changes of ownership, administrative changes, and initial certification work for Skilled Nursing Facilities (SNFs) (January 3, 2022).
- CMS has also streamlined changes of ownership, administrative changes, and initial certification work for *Ambulatory Surgical Centers (ASCs), Community Mental Health Centers (CMHCs), Comprehensive Outpatient Rehabilitation Facilities (CORFs), FQHCs, Home Health Agencies (HHA), Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP), and Portable X-Ray (PXR) Providers (May 30, 2022).*
- The State Operations Manual (SOM) and Program Integrity Manual (PIM) will be updated to reflect these changes later.
- The attached standard operating procedure (SOP) related to changes of ownership (CHOWs), administrative changes, and initial certification enrollment work *for the providers and suppliers listed above and the remaining providers/suppliers transitioning, which are:*
    - *Hospitals (including Psychiatric Hospitals and Transplant Programs)*
    - *Hospices*
    - *End Stage Renal Disease (ESRD) Facilities*
- *CMS has also clarified the main SOP for all impacted providers/suppliers and added guidance for Accrediting Organizations (AOs). The revisions are reflected in red italics.*

Background and General Overview

To improve the enrollment process for Medicare-participating certified providers and suppliers, CMS is transitioning certain certification-enrollment functions performed by the CMS Locations to CMS' CPI/PEOG and the MACs. The workload transition will continue with implementation rollouts projected throughout CY2022.

The SOP provides a general overview of processing instructions for:

- Changes of Ownership (CHOW);
- Administrative Changes, also known as Changes of Information (such as address changes, name changes, additional service locations, relocations, etc.); and,
- Initial Certification.

The SOP identifies processing instructions and highlights the applicability of all providers/suppliers impacted, which will be transitioned. This process commenced with Skilled SNFs on January 3, 2022, *and* **ASCs, CMHCs, CORFs, FQHCs, HHAs, OPT/OSP, and PXR** *on* **May 30, 2022**. ***This release includes*** **the remaining providers/suppliers** ***scheduled to transition on November 7, 2022.***

This guidance applies to all CMS-855 applications that have not yet been forwarded to the CMS Location with a recommendation from the SA. This includes all new CMS-855 applications received by the MAC and any certification packets recommended for approval by the MAC but are currently in a pending status with the SA.

For all final determinations, the CMS Location will be copied on communications between the State Agency (SA), Accrediting Organization (AO), and MAC **for three months** ***from each transition phase*** unless otherwise notified. The CMS Locations and CPI/PEOG will transition this work by provider and supplier types to ensure consistency by the SAs and MACs.

CHOWs- Part I of the SOP

A CHOW occurs when the responsible legal entity that was a party to the Medicare provider agreement ("Seller") has changed, and the responsible new legal entity ("Buyer") receives/accepts automatic assignment of the existing provider agreement (see 42 CFR 489.18). The responsible legal entity is the party having ultimate responsibility and liability for the operational decisions of the institution. A CHOW may involve any transfer of a provider or supplier even if no money changes hands – the terms "Seller" and "Buyer" are used for convenience.

A CHOW (i.e., when there is an automatic assignment to the new owner of the existing Medicare agreement) does not require a survey. A buyer is generally assigned the existing provider/supplier agreement and its corresponding CMS Certification Number (CCN) if the buyer purchases a participating provider organization and accepts automatic assignment of the existing agreement.

When a CHOW occurs, the new owner/buyer may also reject the automatic assignment of the existing Medicare agreement resulting in the voluntary termination of the CCN and completion of an initial enrollment application by the new owner/buyer.

Administrative Changes- Part II of the SOP

Many enrollment certification actions are administrative changes and not CHOWs. The SOP provides a general overview of what CMS categorizes administrative changes for this certification transition to CPI/PEOG and the MAC.

Administrative changes may include:

- Address changes (not relocations);
- Adding/Removing a Branch Location;
- Additional Practice Locations/Sites;
- Adding Additional Services;
- Cessation of Business;
- Expansions/Removal and Change in Modalities and Services (ESRD only)*;
- Extension Locations;
- Multiple Locations; and,
- Name Changes.

*Does not require a CMS-855.

These administrative changes require a SA review to determine the need for a survey. For instance, the SA may evaluate the need for an onsite survey for a provider/supplier that has submitted an updated CMS-855A or CMS-855B to change location. The relocation may be a change in a location outside of the existing geographical area and no longer serves the same patient populations and may warrant a survey.

Additional certification work includes relocations. A change in a location outside of the primary approved site or a change in a location outside of the existing geographical area is considered a relocation of a provider/supplier. A relocation request must ensure that patients/residents will continue to receive uninterrupted service during the relocation. The general SOP outlines the responsibilities of the SA and AO (for deemed facilities), CPI/PEOG, and the MAC for relocations. While not all relocations require the SA or AO to conduct a survey, relocations often mirror administrative changes, or administrative changes may be determined to be a relocation.

We note that for deemed facilities, the SA will be responsible for updating the facility information in the national database system based on the recommendations of the AO and final approval letters issued by the MAC.

If a provider/supplier is requesting an administrative change that may occur close to their recertification/reaccreditation survey, the provider/supplier should be made aware that this request follows the transition steps (e.g., CMS-855 to the MACs). For survey efficiency, if the SA or AO determines the administrative change warrants a survey, the SA or AO may combine the recertification/reaccreditation survey with the administrative change. However, if surveys are combined, the SA/AO would follow existing processes for submission of recommendations of approval/denial through the CMS Locations (e.g., recertifications are not being transitioned). If combined, the SA/AO would need to submit a recommendation of approval/denial of the administrative change via the transition process/steps outlined within this SOP. After survey completion, recertifications and administrative changes would be processed according to their nature. There may be two separate communications- one to the CMS Locations (recertifications) and one to the MAC (admin change).

If the SA or AO is notified or notices during the survey that an administrative change is present, the SA/AO must direct the provider/supplier to submit the CMS-855 to the MAC (except ESRD facilities change in modalities). The administrative change approval effective date may not be before the MAC's initial recommendation of approval of the CMS-855 even if the survey is conducted before the notice to the MAC of the requested administrative change via the CMS-855. Providers/suppliers should be informed of the enrollment and certification process so they do not have unrealistic expectations about the effective date of their provider or supplier agreement with Medicare, e.g., an applicant should not expect its effective date to be the date it submitted its enrollment application.

Initial Certification and Enrollment- Part III of the SOP

Except for Federally Qualified Health Centers (FQHCs), which were transitioned in March 2021 (see Admin-Info 21-06-ALL), all providers and suppliers are surveyed for compliance with the Medicare conditions of participation, conditions for coverage, or requirements. Initial certification and enrollment require a multistep process that already includes CPI/PEOG and MAC involvement related to enrollment activities and the CMS-855A or CMS-855 B processing when a provider/supplier has been recommended for approval to participate in the Medicare Program. In short, the MAC receives the prospective provider/supplier CMS-855A or CMS-855B, recommends approval to the SA, which in turn conducts the applicable health survey and (as applicable) Life Safety Code (LSC) survey, and forwards the completed application package and recommendation to the MAC for approval. We have streamlined the initial enrollment and certification activities within this SOP into a general process for the SA, CPI/PEOG, and the MAC.

We note that for deemed facilities, the SA will be responsible for updating the facility information in the national database system based on the AO's recommendations and the MAC's final approval letters. Once the national database system is updated, the SA forwards the CMS-1539 to the MAC for final processing, as appropriate.

For AO guidance on handling existing Medicare-participating facilities and changes in deemed status (e.g., initial surveys with CMS Certification Numbers or termination of deemed status), please refer to Admin Info 23-02-ALL.

Certification & Enrollment Activities Not Transitioning

CMS **will not be changing the current** enrollment and certification activities for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID), Psychiatric Residential Treatment Facilities (PRTFs), and Nursing Facilities (NFs), as these providers are Medicaid-only, and therefore will continue to follow the existing processes. Neither the MAC or CPI/PEOG are involved in processing these applications. The SA will communicate directly with the State Medicaid Agency (SMA) for dually-certified facilities.

At this time, we are also not transitioning enrollment and certification activities for Critical Access Hospitals (CAHs), Religious Nonmedical Health Care Institutions (RNHCIs), Organ Procurement Organizations (OPOs), Rural Health Clinics (RHCs), *or Rural Emergency Hospitals (REHs)*. Any potential change to enrollment and certification activities of these providers/suppliers will be communicated in the future. We do not include Special Purpose Renal Disease Facilities (SPRDF) as these are only used in emergencies/disasters. Note the MACs will continue to receive Tie-In Notices (CMS-2007) from the CMS Locations for these providers and suppliers.

Additionally, for U.S. Territories (American Samoa; the Commonwealth of the Northern Mariana Islands; Guam, and the U.S. Virgin Islands), the CMS Locations will act as the State Survey Agency; the MAC will forward any recommendations for approval to the San Francisco or New York CMS Location, as appropriate. AOs will also send any recommendations for approval or denial through these CMS Locations, as applicable, for initial surveys.

Finally, we further note there is no change in existing processes for any provider/supplier waiver requests.

Accrediting Organizations

For CHOWs, AOs will be copied on all communications between the provider/supplier, the SA, and the MAC. There will be no direct involvement from the AOs in recommending approval or denial of a CHOW.

For administrative changes, the MAC will provide the initial approval recommendation to the SA and AO (if applicable). The AO will determine survey needs and recommend approval or denial directly to the MAC, copying in the SA. SA surveys are scheduled based on the Mission & Priority Document. For AO surveys, the AOs are not held to the MPD requirements. However, the AO must generally communicate the intent to survey the SA within 30 business days. This is the only activity in which the AO communicates directly with the MAC.

For initial surveys, specifically for providers and suppliers seeking deemed status through a CMS- approved AO, the provider/supplier will first submit their CMS-855 through the general enrollment process to the MAC, which will copy the AO and SA on the initial approval recommendation based on enrollment. However, the AO will conduct the initial survey. An AO may not conduct an initial certification survey of a prospective provider or supplier for Medicare certification purposes *until the MAC has provided its recommendation to the SA and the AO.* The SAs will be responsible for entering information on the 'Deemed' tab within the certification kit in the national survey database system only for those initial applicants seeking deemed status based on accreditation under a CMS-approved Medicare accreditation program.

Finally, if a facility voluntarily withdraws its accreditation status, the AO must notify the SA and copy in the CMS Location. In the event of withdrawal of accreditation status or when a facility changes from one AO to another, the SA will be responsible for updating the national database to reflect the accreditation status. We also note that for AO denials of accreditation or a facility being involuntarily withdrawn from accreditation (the facility would be under the SA jurisdiction), notifications of these changes should be sent directly to the SA and copy in the CMS Locations. *Also, refer to additional guidance within Admin Info 23-02-ALL.*

The SA will be responsible for updating the national database system for changes in accreditation status. This is not considered a voluntary termination and does not require any action from the MAC or CPI/PEOG.

General – Differences between Site Visits and Surveys

MACs are multi-state, regional contractors responsible for administering Medicare Part A and Medicare Part B claims. MACs may conduct "site visits" as part of the enrollment process for Medicare-participating providers/suppliers. MAC site visits serve to verify that the enrollment information submitted to CMS or its agents is accurate and to determine compliance with Medicare enrollment requirements. Site visits for enrollment purposes do not affect those site visits performed to establish compliance with participation conditions.

In accordance with § 424.517, based upon the results of CMS onsite review, the provider may be subject to denial or revocation of Medicare billing privileges as specified in § 424.530. These site visits differ from surveys conducted by the SAs, CMS Locations, or AOs (if applicable). Providers/suppliers may receive notice from the MAC about site visits separate from this process.

Conclusion

The existing process of enrollment and certification actions primarily follows the following process:
Provider/Supplier > MAC > SA > SOG > SA (and AO if applicable) > MAC >Provider/Supplier

With the streamlined initiative and the successful transition of these enrollment and certification activities, the process will be:
Provider/Supplier > MAC > SA (and AO if applicable) > MAC/PEOG >Provider/Supplier

We believe this will provide a more timely response to the needs of providers and suppliers and reduce unnecessary burdens. **The SOP outlines the general processing instructions for all parties involved, and the addendums cover the provider/supplier differences and specific information. The SA is to continue to utilize the Form CMS-1539 (or comparable form for the AO) as the transmittal form for communicating recommendations to the MAC.**

Training

The streamlined enrollment and certification work outlined in this memorandum and SOP was provided on October 28, 2021. CMS recorded the training and distributed the training slides and recording through the Association of Health Facility Survey Agencies (AHFSA) for the SAs. As aforementioned, the CMS Locations will remain copied for three months post- implementation to ensure a smooth transition and provide technical assistance to CPI/PEOG and the MAC.

CMS also supports engagement in these transition processes through monthly calls with the SAs, SOG, MACs, CPI/PEOG, and the AOs.

Resources

CMS has developed SOPs to assist all involved parties in processing certification transactions. The SOM will be updated according to the SOP once the transition of the enrollment and certification processes has been completed for all applicable provider/supplier types. **An updated Form CMS-1539 transmittal and contact information** for the SAs, AOs, and MACs is available on the Quality, Safety and Oversight Group (QSOG) website at:
https://www.cms.gov/Medicare/Provider-Enrollment-and- Certification/CertificationandComplianc

Contact: For questions or concerns relating to enrollment, please contact ProviderEnrollment@cms.hhs.gov.

For questions or concerns relating to the certification transition process and the standard operating procedures within this memorandum, please contact QSOG_Certification@cms.hhs.gov.

Please contact your applicable CMS SOG Location for questions or concerns about certification regulations.

Effective Date: *The effective date of this remaining transition will commence on November 7, 2022.* This information should be communicated with all survey and certification staff, their managers, and the State/CMS Location training coordinators within 30 days of this memorandum.

/s/

Karen L. Tritz
Director, Survey & Operations Group

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

Attachments –

1- CMS Standard Operating Procedures- CHOW, Administrative Changes, Relocations & Initials
2- SNF Addendum to the Standard Operating Procedures
3- ASC, CMHC, CORF, FQHC, HHA, OPT/OSP, PXR Addendum to the Standard Operating Procedures
4- ESRD Facilities Addendum to the Standard Operating Procedures
5- Hospice Addendum to the Standard Operating Procedures
6- Hospital (including Transplant Programs and Psychiatric Hospitals) Addendum to the Standard Operating Procedures

Attachment 1:
CMS Standard Operating Procedure (SOP)
for Enrollment and Certification Activities

TABLE OF CONTENTS

Purpose: The intent behind this Standard Operating Procedure (SOP) is to provide direction to the Survey Operations Group (SOG) (later referred to as CMS Locations), State Survey Agencies(SAs), Accrediting Organizations (AOs), and the Center for Program Integrity (CPI)/Provider Enrollment Oversight Group (PEOG) and the Medicare Administrative Contractors (MAC) as it relates to the processing of changes of ownership (CHOWs), administrative changes (name, address, branch locations, additional services, relocations, etc.), and initial surveys and enrollment.

We will not be changing the existing enrollment and certification activities for Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID), Psychiatric Residential Treatment Facilities (PRTFs), and Nursing Facilities (NFs) as these providers are Medicaid-only and will continue to follow the existing processes. The SA will communicate directly with the State Medicaid Agency (SMA) for dually-certified facilities. This SOP also does not apply to non-certified providers/suppliers. Neither the MAC or CPI/PEOG have any role in processing or approval of these facilities and they are

not to be copied or involved in these processes.

We are also not transitioning enrollment and certification activities for Critical Access Hospitals (CAHs), Religious nonmedical health care institutions (RNHCIs), Organ Procurement Organizations (OPOs), rural health clinics (RHCs), *rural emergency hospitals (REHs)* or Special Purpose Renal Facilities (SPRDF) as these are used in emergencies/disasters only. Note, the MACs will continue to receive Tie-In Notices (CMS-2007) from the CMS Locations for these providers and suppliers Any potential change to enrollment and certification activities of these providers/suppliers will be communicated in the future.

Additionally, the CMS Locations will continue to act as the SA for U.S. Territories (American Samoa; the Commonwealth of the Northern Marianas Islands; Guam and the U.S. Virgin Islands). The MAC will forward any recommendations for approval to the San Francisco or New York CMS Location, as appropriate. AOs will also send any recommendations for approval or denial through these CMS Locations, as applicable, for initial surveys. *We further note, there is no deviation in the processes outlined within this SOP if a facility is considered tribal/Indian Health Service (IHS).*

For all final determinations related to CHOWs, Administrative Changes, and Initial certifications, the CMS Locations will be copied on communications between the SA, AO, and MACs for **three months** or unless otherwise notified.

Background: CMS continues to conduct activities to simplify the enrollment and certification work. Specifically, CMS is streamlining some enrollment and certification functions for certified providers/suppliers to the CPI/ PEOG and the MAC. The process to date has consisted of streamlining the processing of voluntary terminations and cessations of business on July 27, 2020 (see Admin-Info 20-08-ALL-Revised), as well as enrollment of Federally Qualified Health Centers (FQHCs) on March 15, 2021 (see Admin-Info 21-06- ALL). *CMS transitioned ASCs, CMHCs, CORFs, FQHCs, HHAs, OPT/OSP, and PXR on May 30, 2022 (see Admin Info 22-02-ALL).*

This SOP outlines general procedures in a standardized format for processing these activities. Enrollment aspects of the CHOW process are governed by the Medicare Program Integrity Manual (PIM), Chapters 15 and related Technical Direction Letters (TDLs). **The MAC will continue to follow the timeframes and guidance specified in the PIM.**

Effective Date: *Beginning November 7, 2022, all providers/suppliers aforementioned will be transitioned via this process.* The transition of certification enrollment work related to the processing of CHOWs, administrative changes, relocations, and initial certification will be released in segmented phases by provider/supplier type.

This guidance applies to all CMS-855 applications that have not yet been forwarded to the CMS Location with a recommendation from the SA. Included are all new CMS-855 applications received by the MAC, and any certification packets recommended for approval by the MAC but are currently in a pending status with the SA.

Notifications: *For CHOWs, administrative changes, and initial certifications, the SA is responsible for notifying the Quality Improvement Organization (QIO) of any changes. The QIO is notified of any changes for ASCs, ESRD facilities, hospitals (psych, PPS, or PPS-excluded), hospice, HHA, and OPT/SP. Additionally, the SA and AO (as applicable) is also responsible for notifying the ESRD networks of any changes. These notifications are also required for voluntary terminations.*

Appeals and Reconsiderations: If the SA determines for any of the survey and certification activities in this SOP that the provider/supplier is determined not to be in compliance with Medicare requirements, the SA will notify the MAC via the CMS-1539. **The MAC will** issue the appropriate notifications to the provider/supplier including appeal and/or reconsideration rights, as appropriate. The provider will be directed to contact the SA or the SOG about the reconsideration appeals process should there be any follow up questions from the provider. The SA and CMS Locations remain responsible for the handling all appeal and reconsideration requests related to certification. (Refer to Part IV of this SOP for additional information).

Enforcement: The SA and CMS Locations remain responsible for processing any enforcement actions as a result of noncompliance with the Medicare requirements following the existing processes and transmitting information to the MAC via the CMS-2007 Tie In Notice.

CMS-1539 Form & National Database Updates: The SA and AO (if applicable) must use the CMS Form 1539 or comparable AO form, as a transmittal document to the MAC regardless of use of national database system (e.g. iQIES or ASPEN). *Note: iQIES does not have the CMS Form 1539. SAs and AOs should use the form provided with this SOP.*

PART I- CHANGES OF OWNERSHIP (CHOWs)

Applicability of CHOWs

The requirements related to CHOWs apply to the below listed providers and suppliers. Providers to which CHOW rules apply include (see 42 CFR 489.2):

- Hospitals;
- Skilled nursing facilities (SNFs);
- Home health agencies (HHAs);
- Hospices;
- Comprehensive outpatient rehabilitation facilities (CORFs);
- Clinics, rehabilitation agencies, and public health agencies (only for furnishing outpatient physical therapy and speech pathology services)- referred to as OPT/OSP;
- Community mental health centers (CMHCs) (only to furnish partial hospitalization services);

The CHOW requirements also apply to suppliers, which are subject to survey and certification provisions in 42 CFR Part 488. CMS processes CHOWs for supplier participants that have category- specific supplier agreements with the Secretary and/or for suppliers who file cost reports (ESRD facilities). Specifically:

- Ambulatory surgical centers (ASCs) - section 1832(a)(2)(F)(i) of the Act;
- Federally qualified health centers (FQHCs)- 42 CFR 405.2434
- End-stage renal disease facilities (ESRDs)– 42 CFR 413.198 (Cost Reports).

Portable X-Ray (PXR) suppliers and Transplant Programs are also included within these CHOW activities.

Changes of Ownership (CHOW) General Overview:

A change of ownership (CHOW) occurs when the responsible legal entity that was a party to the Medicare provider agreement ("Seller") has changed, and the responsible new legal entity ("Buyer") receives/accepts automatic assignment of the existing provider agreement (see 42 CFR489.18). The responsible legal entity is the party having ultimate responsibility and liability for the operational decisions of the institution.

A CHOW may involve any transfer of a provider or supplier even if no money changes hands –the terms "Seller" and "Buyer" are used for convenience. The MAC determines if the transaction is a potential CHOW.

A CHOW (i.e. when there is automatic assignment to the new owner of the existing Medicare agreement), per se, does not require a survey. See additional information under the CHOW checklist related to identifying CHOW versus initial certification.

A Buyer is assigned the existing provider/supplier agreement and its corresponding CCN if the Buyer purchases a participating provider organization and **does not reject** automatic assignment of the existing agreement. The CCN is not part of the sale and cannot be sold. A CCN is not the "property" of any individual or legal entity. The CCN is issued by the Medicare program and is under the control of the Secretary of DHHS, subject to law, regulation, and program policy (See Section II of the SOP for buyers who do not reject automatic assignment; Section III provides details if the automatic assignment is rejected).

SECTION I- General Processing Instructions (If a New Owner Does Not Reject Automatic Assignment)

The following steps are taken once the CMS-855 form is submitted:

Step #1: A CHOW situation begins with the respective Buyer (new owner) accepting receiving assignment of the provider agreement submits the CMS-855 to the MAC. The CMS-855 may be submitted by both the Seller and Buyer either online through PECOS or the appropriate paper CMS-855. In accordance with 42 CFR 424.516(e)(1), the enrollment application must be submitted within 30 days for the change of ownership or control, or CMS may impose penalties on the provider or supplier. In the event the MAC only receives the Buyer's CMS-855, the MAC can proceed without the Seller's documentation. Note, the MAC cannot proceed with only the Seller's documentation as the MAC should ascertain that the Buyer does not reject automatic assignment.

Step #2: The MAC will review the CMS-855 for completeness in accordance with PIM instructions.

Step #3: Once the MAC determines that the CMS-855 is accurate based on enrollment criteria, the MAC will provide its recommendation via email to the SA and the AO (if applicable) and include the PECOS Application Data Report (ADR) or paper CMS-855, including the legal documentation (Bill of Sale, etc.) of the CHOW and any additional documentation provided by the Buyer/Seller. **The MAC will send the recommendation and documentation to the SA and copy the AO (if applicable) after the CHOW transaction has occurred and the legal documentation is complete and signed by both parties.**

> **NOTE:** The MAC will verify deemed status and identify the AO based on the information listed on Section 2D of the CMS-855A (Section E for CMS-855B) to provide communication to the AO when applicable. However, AOs will not be directly involved in the processing of CHOW situations unless contacted by the SA for a need for a survey as part of the CHOW package.

Step #4: Once the SA receives the MAC enrollment recommendation, the SA will review the CHOW package from the MAC. The CHOW Package must include the following:

1. Legal Documentation of CHOW- the legal documents that governed the CHOW transaction, sale, or transfer of the Medicare-participating facility from the seller to the buyer, as applicable to the federal CHOW process (separate from any additional licensure requirements).
2. Evidence of the provider's successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR)* portal, as applicable.
3. Provider's signed CMS-1561, CMS-1561A, or CMS-370, as applicable.
4. Request for certification in the Medicare program, appropriate to provider/supplier type (i.e., CMS-1572, CMS-377, CMS-3427, CMS-29, CMS-671, etc.).
5. The National Provider Identifier (NPI) number (may be directly on the CMS-855,however should include the proof of documentation that this number was issued).
6. Other applicable provider/supplier specific documents as outlined in Section V.

IMPORTANT NOTES:

- If items 2, 3, 4, 6 are missing from the documentation CHOW package, **it is the responsibility of the SA, not the MAC, to obtain the required documents from the provider/supplier.** The MAC should only communicate enrollment requirements to the provider/supplier. The SAs must obtain the required documentation.

- **OCR*:** Before an agreement is executed with a provider to participate in the Medicare program or with a provider undergoing CHOW, there must be a determination of compliance with civil rights requirements. OCR conducts necessary investigations and makes determinations related to compliance with the requirements. For OCR attestation, a prospective provider that applies for initial certification in the Medicare program or a buyer of a provider undergoing a CHOW must receive a clearance from OCR noting compliance with the requirements under 42 CFR 489.10(b). To process CHOW requests, the buyer of a current Medicare provider undergoing a

CHOW must send a copy of the electronic verification from the OCR to the SA, or if this is a CHOW of an IHS or Tribal-owned provider, the buyer must send a copy of the electronic verification from the OCR to its CMS Location. For the OCR's online Assurance of Compliance portal, please visit https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf.

- **CHOW and Additional Changes**: In situations where a buyer (new owner) wishes to add additional services (or relocate) as part of the CHOW, the additional services must be specifically identified and the SA must identify whether a survey is to be conducted and include that information in their recommendation along with the primary recommendation for approval of the CHOW to the MAC. For additional information on relocations, refer to Part II of this SOP.

Step #5: After the SA has completed its review, the SA will either:
1) Recommend approval of the CHOW (Step #5A to end); or
2) Recommend denial/non-approval (Step #5B only).

Step #5A: If the SA recommends approval, the SA will send the CHOW package (documents listed above via email) to the MAC with their recommendation to proceed via the CMS-1539. The SA is expected to complete its review within 90 days from receipt of the MAC documentation. If there are circumstances in which the SA would exceed 90 days, the SA is responsible for notifying the MAC of the delay.

The SA must also confirm that the CHOW package identifies if there are any associated changes related to the services provided or the location of the buyer as part of the review. This information is captured on the applicable request for certification in the Medicare program (i.e., specific provider/supplier forms- CMS-1572, CMS-377, CMS-3427, CMS-29, CMS-671, etc.).

Step #5B: **If the SA DOES NOT recommend approval**, the SA will notify the MAC via the CMS-1539 (including justification for non-approval). The MAC will notify CPI/PEOG, who will review the CMS-1539. CPI/PEOG will make the final determination and notify the MAC, who will then provide the notification to the Seller/Buyer. The notification should include a copy to the SA, MAC, and AO (if applicable).

> **NOTE:** If the SA recommends denial, this usually is because the transaction was not considered to be CHOW situation.

Step #6: Once the MAC receives **the SA recommendation for approval of the CHOW,** which confirms that the request is a CHOW, the MAC will provide the approval recommendation and copy of the draft provider letter to CPI/PEOG.

CPI/PEOG will sign the provider/supplier agreement or attestation statement (see provider-specific addendums for specific documentation) and return the information to the MAC to finalize the application. The MAC will send the provider approval letter to the SA and AO (if applicable) and the provider/supplier. *The SA will make the appropriate notifications (QIO/ESRD Networks) as applicable.*

NOTE: The CMS-1539 replaces the tie-in-notice.

Step #7: The CPI/PEOG will update the national database to reflect the CHOW information and effective date based on the MAC notification letter (Step #6).

SECTION II- General Processing Instructions (If a New Owner Rejects Automatic Assignment)

General Instructions for Providers/Suppliers

A new owner (Buyer) may timely reject automatic assignment of the existing provider or supplier agreement, which means that the existing provider or supplier agreement of the Seller is voluntarily terminated effective on the date of ownership transfer. This is not a CHOW.

In these circumstances, if the Buyer wants to be certified to participate in Medicare or Medicaid programs, the Buyer must enroll as an initial applicant, which will follow the procedures outlined under Part IV- Initial Enrollment. There is no appeal process for a voluntary termination if the buyer rejects automatic assignment of the agreement.

Additionally, the Seller would be processed using the Voluntary Termination SOP. The Seller must submit the CMS-855 to the MAC to have the provider or supplier agreement terminated. Medicare enrollment will also be deactivated. The MAC will notify the Seller that the provider agreement has been voluntarily terminated and copy the SA and the AO (as applicable) via email. *The SA will make the appropriate notifications (QIOs and/or ESRD Networks) as applicable.*

SECTION III- General Information

The below outlines general information related to actions in CHOW situations; however, there may be additional information in the by-provider addendums.

A. Deemed Providers and Suppliers & CHOWs

Currently, the majority of CHOW situations within facilities do not require compliance surveys, and the SA is required to verify state licensure and other information per Step #4 (and by-provider addendums). Therefore, AOs will be copied on communications of approval/denial from the MAC to the provider/supplier **(per Part I, Section I, Step #6).** The MAC should verify the AO based on the CMS-855.

B. Situations which May or May Not require a Survey

In a CHOW situation where the new Owner/Buyer does not reject (i.e. accepts) assignment, generally, no survey would be conducted as the new Owner/Buyer is accepting the organization “as is” (which would result in no changes to staff, building, operations, etc.). However, if the SA or AO determines there are quality of care or other concerns or in the event the CHOW includes staff or building changes, this may trigger a survey to be conducted.

The SA or AO (if applicable) determines the need for survey in a CHOW situation upon receipt of the MAC recommendation and during its review (Step #4). For deemed facilities, the AO would conduct a survey for compliance after the CHOW occurs. **AOs will now be copied on all communications by the MAC and SA. The AO may survey its accredited facility at any time without impact to the CHOW process. If the SA determines quality concerns may be present during the CHOW review, it may reach out to the AO to survey and/or survey the facility itself.**

The MACs do not make the determination on survey needs. The MAC must wait until it receives the recommendation from the SA or AO (if applicable), per Part I, Section I, Step#5B or 6.

Surveys are at the discretion of the SA or AO (if applicable) for CHOW situations. Situations in which a survey may be conducted include but are not limited to the following:

- Relocation associated with a CHOW situation (including Part II, Sections II & III of the SOP-Administrative Changes);
- Merger/Acquisitions;
- Facility history of non-compliance;
- SA concerns that the quality of care has/may decline.

C. CHOWs versus Provider Agreement Termination

- In a CHOW situation, the provider agreement is automatically assigned to the new owner/Buyer (see Part I, Section I). The Buyer is subject to all applicable statutes and regulations and to the terms and conditions under which it was originally issued (42 CFR489.18(d)).
- However, the Buyer has the option to reject the automatic assignment of the agreement (see Part I, Section II) and may choose to enroll in Medicare as an initial applicant and seek initial certification. If the Buyer makes that choice, then when received the old owner's/Seller's enrollment application must be processed as a voluntary termination of the existing Medicare provider agreement effective the date of the transaction/sale/transfer of ownership or operations.
    - In this circumstance, the Seller will be required to submit a CMS-855 voluntary termination application which will be processed by the MAC. In the event the Buyer rejects automatic assignment, and the MAC does not receive the Seller's CMS-855, the MAC must reach out to the Seller for this information. The voluntary termination will be effective the date the transaction (legal date of transaction) occurred.
    - It is critical the SA be involved in the event patients require transfers in order to ensure necessary transfers are conducted prior to the effective date of the voluntary termination of the Seller.

D. TYPES OF CHOWS

- **Acquisitions & Mergers:** An acquisition occurs when a currently enrolled Medicare provider is purchasing another enrolled Medicare provider and then makes the acquired provider a part of the acquiring provider. Often termed a "merger," this is an acquisition-combination of Medicare providers, defined below (see SOM Chapter 3,

section 3210).

- **Acquisition-Combination of Medicare Providers** - When the direct owner or entity in direct control of existing Medicare Provider A purchases or otherwise acquires direct control of a second Medicare Provider B and then seeks to combine the two providers under Provider A's Medicare provider agreement and CCN. In order for an acquisition-combination to take place, the providers must meet the specific rules for that provider type and must integrate into a single entity under a single Medicare provider agreement.

  The change in the direct owner or legal entity in control of Medicare Provider B will be a CHOW situation for Medicare Provider B.

  These transactions involve at least two distinct, certified facilities (e.g. two hospitals). In an acquisition-combination of two certified facilities, one CCN will be retired, and that location will usually become a practice location for the surviving CCN. The surviving facility, Medicare Provider A in the example above, must accept the assignment of Medicare Provider B's provider agreement. Medicare Provider B's CCN is retired, and its provider agreement is subsumed into that of the new owner, Medicare Provider A. Only Medicare Provider A's CCN and tax identification number remain.

  In short, if the two facilities are originally owned by two different legal entities, a CHOW must occur first because there must be common ownership before a combination can occur.

  If two facilities already have the same owner, the combination can occur because there is already common ownership. This is not a CHOW, just a combination of two providers into one.

  NOTE: If Medicare Provider A rejects assignment of Medicare Provider B's Medicare agreement, then Medicare Provider B is considered to be voluntarily terminated from the Medicare program. A survey of the terminated location (by the SA or AO, if applicable) is required before Medicare Provider A can be reimbursed for services provided at that location.

E. Relocation versus CHOW (See Part II –Administrative Change- of this SOP for additional information)

- A new owner (buyer) may propose to relocate the provider/supplier concurrent with the CHOW.

- In the event the MAC identifies that the new owner (buyer) wishes to relocate as part of the CHOW (e.g. CMS-855), the MAC will provide this information to the SA (via email) and AO (if applicable) to make a determination on whether or not a survey is required; or whether a CHOW package can be approved without survey. The SA or AO (if applicable) may determine this by reviewing the documentation

and asking the following questions, at a minimum:

- Is the facility serving the same population (i.e. mileage range, same geographic area, etc.)?
- Is the facility utilizing the same personnel?
- Is the facility providing the same or similar services?

- **If one or more of above questions are answered "yes,"** then this would be considered a CHOW and relocation determined by the SA. Generally, if the same population, same personnel, same services, etc., exists, the SA or AO (if applicable) may be able to approve the relocation without an onsite survey. In this case, the SA will follow the steps outlined in Part I, Section II above related to processing CHOWs AND include both the approval recommendation for the CHOW and for the relocation (Part II, Section II of the SOP) in the package to the MACs. This will only occur if the new owner (Buyer) **does not reject** automatic assignment of the provider agreement. It is the SA's responsibility to provide both the CHOW and relocation approval recommendation to the MAC at the same time on one CMS-1539 form. The SA must ensure the CMS-1539 clearly states that the CHOW included a relocation that is approved as part of the CHOW.

- **If any answer to the questions above is "no" or "unknown,"** the SA will request additional documentation from the provider/supplier, potentially schedule a survey, and/or recommend denial to the MAC.

SECTION IV- CMS Certification Numbers (CCNs) & Effective Dates

A. CMS Certification Number (CCN) - General Guidance

For CHOWs in which the new owner/buyer receives automatic assignment of the provider agreement, the CCN will generally remain the same. **CPI/PEOG is required to verify the additional CHOW information and update the national database system with the effective date. The SA will update any other relevant information in the national database.**

For ownership transfers in which the new owner/buyer **rejects** the automatic assignment and the MAC is notified by the SA (See Part I, Section II), the MAC will process the voluntary termination in accordance with existing guidelines on Voluntary Termination in the PIM. For additional information, please refer to the Voluntary Termination SOP.

B. Effective Dates- General Guidance

- In general, a CHOW recognized by the Medicare program is considered to have taken place at 12:01 a.m. on the date specified (i.e., in the first minute of the 24-hour day). Legal responsibility and the right to payment changes over when the clock moves past midnight into the CHOW effective date. (See TDL-210006 *Processing Medicare Part A Provider CHOWs and Terminations,* issued to the MACs on 10-05-2020)

- Providers/Suppliers must provide notice to the SA and MAC related to a prospective CHOW as outlined in Step #1. In every case, the SA and MAC must wait to process the CHOW until after the legal transaction of the CHOW has taken place. **The MAC should follow existing guidance on setting the effective dates (refer to PIM, Chapter 10).**

- If the new owner rejects assignment, the CCN that is associated with the rejected agreement (the Seller's) also terminates effective on the date of the ownership transfer.

SECTION V- By-Provider/Suppliers Differences

The below provides the general overarching guidance and forms related to specific providers and suppliers. We note additional information will be found in each addendum.

NOTE: For all Questionable Transactions, the MAC should send/coordinate with the SA and/or CMS (CPI/PEOG).

A. Ambulatory Surgical Centers (ASCs):

For ASCs, the CHOW package includes the following documents: CMS-855B - Enrollment Application; Legal Documentation of CHOW; CMS-377 - ASC Request for Certification in the Medicare Program; CMS-370 - ASC Benefits Agreement.

B. Comprehensive Outpatient Rehabilitation Facilities (CORF)

For CORFs, the CHOW package includes the following documents: CMS-855A - Enrollment Application; Legal Documentation of CHOW; CMS-359 - CORF Report for Certification to Participate in the Medicare Program; CMS-1561 - Benefits Agreement; and confirmation of eOCR Submission.

C. Community Mental Health Centers (CMHCs)

For CMHCs, the CHOW package includes the following documents: CMS-855A -Enrollment Application; Legal Documentation of CHOW; and CMS-1561 Benefits Agreement.

D. End-Stage Renal Disease (ESRD) Facilities

For ESRD facilities, the CHOW package includes the following documents CMS-855A -Enrollment Application; Legal Documentation of CHOW; CMS-3427 - ESRD Application/Notification and Survey & Certification Report. The MAC will also need to verify the number of In-Center Hemodialysis Stations and modalities (In-Center Hemodialysis; In-Center Peritoneal Dialysis; Training and Support for Home Hemodialysis; Training and Support for Home Peritoneal Dialysis (CAPD/CCPD)).

E. Hospitals

For hospitals, the MAC must verify that the CHOW package includes the following documents: CMS-1539 - Certification & Transmittal; CMS-855A -

Enrollment Application; Legal Documentation of CHOW; CMS-1561 - Benefits Agreement; Confirmation of eOCR Submission. The CHOW package must also identify if the Hospital has Excluded Units (Rehabilitation Unit; Psychiatric Unit; Swing Beds) or a Transplant program. Note: Transplant programs are included as part of a hospital CHOW. Transplant programs cannot undergo a CHOW outside of the hospital, as it's not a separate provider; it's a service of the hospital.

F. Home Health Agencies (HHA)

For HHAs, the MAC must verify that the CHOW package includes the following documents: CMS-1539 - Certification & Transmittal; CMS-855A - Enrollment Application; Legal Documentation of CHOW; CMS-1572 - Home Health Agency Survey & Deficiencies Report; CMS-1561 - Benefits Agreement and confirmation of eOCR Submission. The CHOW package must also identify if the HHA provides any of the following services: Skilled Nursing; Physical Therapy; Speech Therapy; Occupational Therapy; Medical Social Services and Home Health Aide Services (see Form CMS- 1572).

NOTE: For HHAs, unless an exception under 42 CFR 424.540(b)(2) applies, CHOWs may only occur 36 months after the effective date of the HHA's initial enrollment or most recent change to majority ownership. HHAs may not undergo a CHOW (the provider agreement and billing privileges do not convey to the new owner) within 36 months of their initial enrollment. Additionally, for HHAs with branches that fall under the parent's Medicare provider agreement and CCN, **if a new owner rejects automatic assignment** of the existing Medicare agreement, the HHA, including its branches, is terminated. (Refer to the HHA addendum for additional information).

G. Hospice

For Hospices, the MAC must verify that the CHOW package includes the following documents: CMS-1539 - Certification & Transmittal; CMS-855A - Enrollment Application; Legal Documentation of CHOW; CMS-417 - Hospice Request for Certification in the Medicare Program; CMS-643 - Hospice Survey & Deficiencies Report; CMS-1561 - Benefits Agreement and confirmation of eOCR Submission.

NOTE: For Hospices, multiple locations fall under the parent Hospice's Medicare provider agreement and CCN. The provider agreement of the hospice, including its multiple locations, terminates **if a new owner rejects automatic assignment** of the existing Medicare agreement.

H. Skilled Nursing Facilities (SNF)- Long- Term Care

SNF CHOWs often take the form of a new operator. The documentation of the CHOW transaction is the operating transfer agreement, from the old operator to the new operator. This is still a CHOW. Even though the operator does not own the building, it is still the entity with legal responsibility for the operation of the nursing home provider itself.

For SNFs, the MAC must verify that the CHOW package includes the following documents: CMS-1539 - Certification & Transmittal; CMS-855A - Enrollment Application; Legal Documentation of CHOW; CMS-671; CMS-1561 - Benefits Agreement and confirmation of eOCR Submission; Patient Transfer Agreement that shows the buyer as a party to the agreement and outlines procedures for a hospital to admit the nursing home residents when they need acute care (§ 483.70 (j)).

I. Federally Qualified Health Centers (FQHCs)

For FQHC's, the MAC must verify that the CHOW package includes the following documents: CMS-855A - Enrollment Application; Supporting Legal Documentation that a CHOW occurred. The CHOW Package should also include HRSA Grant Information (HRSA Grant should have the name of the new grantor/new Buyer).

The following constitutes an FQHC CHOW (42 CFR § 405.2444):

(1) Incorporation. The incorporation of an unincorporated FQHC constitutes a CHOW.

(2) Merger. The merger of the FQHC corporation into another corporation, or the consolidation of two or more corporations, one of which is the FQHC corporation, resulting in the creation of a new corporation, constitutes a CHOW. (The merger of another corporation into the FQHC corporation does not constitute a CHOW.)

(3) Leasing. The lease of all or part of an entity constitutes a CHOW of the leased portion.

NOTE: For FQHCs, no CMS-1539 will accompany the CHOW package as there is no SA involvement. Once the MAC has conducted the initial review of the FQHC CHOW, CPI/PEOG will conduct the final review and make the final determination.

J. Portable X-Ray (PXR)

For PXR, the MAC must verify that the CHOW package includes the following documents: CMS-1539 - Certification & Transmittal; CMS-855B - Enrollment Application; Legal Documentation of CHOW; CMS-1880 - Request for Certification as a Supplier of PXR Services under the Medicare Program.

K. Outpatient Physical Therapy/Speech Pathology (OPT/SP)

For OPT/OSPs, the MAC must verify that the CHOW package includes the following documents: CMS-1539 - Certification & Transmittal; CMS-855A - Enrollment Application; Legal Documentation of CHOW; CMS-1856 - Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services; CMS-1561 - Benefits Agreement and confirmation of eOCR Submission.

OPT/OSP providers often have extension sites. Refer to the specific addendum.

SECTION VI- Important Reminders

- General Rule: CMS does not allow parties to use complex legal agreements to circumvent the CHOW rules, which apply to all providers and those suppliers subject to survey and certification. Specifically, a new owner may not both reject assignment of the provider/supplier agreement and its responsibilities yet still obtain the uninterrupted Medicare participation provided by a CHOW.

- In the event of a cessation of business (generally over 30 days of closure), the SA will review and consult as needed with the SOG location. There can be no CHOW, i.e., transfer of Medicare certification, assignment of the provider agreement, and transfer of the CCN if there is no functioning provider enterprise in existence. If a provider ceases operations, it is considered a cessation of business and would be treated as a voluntary termination. Cessation of business situations will be reviewed and managed on a case-by-case basis by the SA.

- Temporary Closures will be reviewed by the SA and SOG Locations on a case-by-case basis. If a provider anticipates more than 180 days on their initial request of a temporary closure, the SOG location will generally deny the temporary closure and advise the provider to submit a voluntary termination. For requests greater than 30 days, a Tie-Out Notice is submitted to the Medicare Administrative Contractor (MAC), authorizing the anticipated time-period the Provider will be non- operational. Submitting the Tie-Out notice prevents claims from being filed in error when the provider is non-operational.

- A provider sometimes experiences an addition or deletion of personnel, not under a partnership, but a CHOW does not occur. In these instances, the MAC will generally process the changes without SA involvement, per Chapter 10 of the PIM.
- In a CHOW, no payment goes to the new owner's bank account until CMS has approved the CHOW. Until that process is complete, payments to the provider will continue to go to the prior owner's bank account. The parties to a sales or other transfer agreement must provide for the distribution of payments issued during the CHOW processing period for services after the effective date of the CHOW. If the new owner wants all payments to go to its own bank account, it should begin submitting claims after the MAC notifies it that the CHOW processing is complete. See PIM, Chapter 10.

- For U.S. territories, the steps outlined under the processing section for Section I and Section II above still apply, however the CMS Locations will be responsible for processing CHOWs with the MAC and CPI/PEOG in lieu of the SAs.

Part II –Administrative Changes

Section I- General Information

Many enrollment and certification actions are not CHOWs. These situations are generally when a provider/supplier changes names, not due to a CHOW, or there is an administrative update to the provider agreement. All of these activities, with the exception of ESRD additional services/modalities, will require submission of the CMS-855.

The MAC currently processes address changes (not relocations) and name changes without requiring review/recommendation for approval by the SA and AO (if applicable). **The MACs use existing practices for making determinations for actions that do not require SA or AO involvement. In cases where uncertainty exists for address changes or name changes, the MAC should consult with the SA or AO, as applicable.** In general, for these two administrative changes, the MAC will process the transactions without involvement from the SA or AO unless the request appears to have additional associated changes listed in Section II below. **In these instances, the MAC must copy the SA and AO (if applicable) in any communications or approval (as licensure information may need to be updated).** For approvals issued by the MAC, the SA will be responsible for updating the national database as required except for the effective and or termination dates, which will be updated by CPI/PEOG, and AOs will update ASSURE as required.

- **Address Change (Not Relocation):** An address change which is not a relocation may be as a result of street name changes; zip code changes; suite number changes, but not a change to physical location.

- **Name Changes**: Name changes of an organization may occur that are not as a result of a CHOW, but rather changes of Owners (see Part I, Section I.B.). These may be changes to the owner's information or the organization name as a whole.

Section II- Defining Administrative Changes

As CMS streamlines some of the activities to CPI/PEOG and the MAC, these administrative changes will be captured within each provider/supplier type addendum as it applies. There are specific processes for these changes, which will be highlighted in the provider/supplier addendum. The below provides only a general overview of administrative changes, which are not CHOWs (Part I) or Initial Certification/Enrollment (Part III). For the below activities, which the MAC will not automatically process, the MACs will send a recommendation for approval to the SA or AO. Recommendations of approval by the MAC require SA or AO action as outlined below within Part II of this SOP.

Adding/Removing Sites, Services, or Locations:

- **Additional Sites (Practice Locations)**: CORF, HHAs, Hospitals, Hospices, and OPT/OSPs may request additional practice locations. Additional locations of these providers and suppliers are part of the parent company/organization but are at

another location. Additional services are usually added when a provider/supplier requests an additional location/site or extension location but may also arise at the parent/primary site. An organization may apply to CMS for approval of another location near the primary/parent site for the purpose of providing additional access to care. These changes are submitted on the CMS- 855.

NOTE: For provider/suppliers who "drop" or wish to close an additional location or site, the provider/supplier would send the request to the MAC in a CMS-855, or the SA may advise the MAC by completing the CMS-1539. For deemed providers/suppliers, communications may also be from the AO to the MAC (copying in the SA) via a comparable CMS-1539 notification. (Generally, closure/dropped locations will be processed as voluntary terminations of the location- **but not the entire CCN/provider**).

- **Branch Location for HHAs:** A branch office is an approved location or site from which an organization provides services within a portion of the total geographic area serviced by the parent organization. These branch locations are required to furnish information on the form CMS-855A identifying the geographic area(s) where health care services are rendered. There will be circumstances in which a branch office/location will need to be added or removed.

- **Extension Locations (Extension Sites) for OPT/OSPs:** These locations are additional practice locations; however, they are only applicable to rehabilitation agencies. These locations are defined in 42 CFR 485.703. Note, for OPT/OSP, these are similar to the branch locations but are called extension sites.

- **Multiple Locations for Hospices:** When an existing Hospice intends to add a multiple location, it must notify the SA and submit a CMS-855A. Multiple locations for Hospices are similar to HHA branches.

- **Expansions/Removal and Change in Modalities and Services for ESRD Facilities:** These changes are only applicable to ESRD facilities. When an ESRD facility wishes to increase the number of its approved in-center dialysis stations or add a modality/service, it must submit a new Form CMS-3427 ESRD Application and Survey and Certification Report to the applicable SA. The dialysis facility must specify the service requested or the number of additional stations requested and include evidence that adequate space is available for the stations in consideration of safety and infection control and a summary explanation of any building renovations that will be necessary for the addition of stations.(See SOM Chapter 2, Section 2280 - ESRD Survey Activities).
  - This is the only administrative change that does not require a CMS-855 to be sent to the MAC. The provider/supplier will be required to submit the CMS 3427 form to the SA and AO (if applicable) who will review, determine survey needs, and recommend approval/denial to the MAC. (The steps will follow the general SOP guidance in Part II, Section III, but begin at Step #5 once the SA and AO (if applicable) receives the ESRD facility request). The SA and AO (if applicable) will need to notify the MAC of a change in modalities and services via the CMS-1539 (comparable for AO).

- The MACs need to update relevant information for billing purposes, therefore will send the final approval/denial letter to ESRD facility consistent with the steps below.

Cessation of Business:

There are instances in which surveyors may arrive at a facility to conduct a re-certification survey and find that there are no patients or the organization is no longer at the location on the CMS-855. If a provider relocates and is no longer the same provider (different staff, services, patients), then it is a cessation of business (voluntary termination).

Change in Location/Relocation:

A change in location or relocation that is outside of the primary approved site or change in a location outside of the existing geographical area is considered a relocation of a provider/supplier. A relocation request must ensure that patients will continue to receive uninterrupted service during the relocation. A relocation may or may not need a survey.

NOTE:

- If a provider/supplier requests a change in a location that is out-of-state or ceases to serve the same community, this is not a relocation but must be processed as a voluntary termination, and the provider/supplier would need to be processed as an initial applicant (initial enrollment).
- As part of the steps outlined in Part IV, if the SA is denying the relocation of a main site, this is considered a termination. If it's an additional site denial (extension, branch, and multiple location), then there's no termination. **The MAC will follow PIM guidance in Chapter 10 related to denials.**

The following "Administrative Changes" will remain a responsibility of the CMS Location sand SAs to review and process

- **Conversions:** Provider conversions such as Hospital to CAH; RHC to FQHCs, or OPTs to CORFs will remain the responsibility of the CMS Locations and SAs.

- **Temporary Closure**: If the organization undergoes a temporary closure, due to repairs, remodeling, or facility emergency for a period of time; it must notify the SA in writing. A temporarily closed facility may not retain its Medicare participation indefinitely. At the time of the temporary closure, the facility provides a projected date for resumption of services. The projected time frame for closure must be consistent with the repairs, renovation, or any other information supporting a "temporary" closure. Depending on the duration, closure may be viewed as a cessation of business (voluntary termination of the Medicare CCN). The facility may be asked to submit periodic progress reports to the SA as to whether the projected re-opening remains the same. Temporary closures will be reviewed by the SA and CMS Location. **AOs may not approve temporary closures. In the event of a deemed facility requesting temporary closure, the provider/supplier must be redirected to the SA.**

Section III- General Processing Instructions for CMS

While some documentation may vary based on the type of administrative request, the steps below provide a general overview on how the documentation will be processed by the responsible parties (SA, AO (if applicable), CPI/PEOG, and the MAC). Additional information for these actions will be outlined in the applicable provider/supplier addendums.

Step #1: An "administrative change" situation begins with the respective provider/supplier submitting a revised Form CMS-855A or CMS- 855B to the MAC. The CMS-855 is commonly submitted online through PECOS, there are still times in which the application comes in paper-based. In the majority of administrative changes, the submission of the Form CMS-855 occurs after the change has been completed by the provider/supplier, with exception of adding stations/modalities (ESRD).

> **NOTE:** For ESRDs, a request for Removal and Change in Modalities and Services is completed via the CMS-3427 Form, not the CMS-855 (refer to ESRD addendum, when released). For this change, the communication will start from the provider to the SA or AO (if applicable).

Step #2: The MAC will review any applicable enrollment requirements per PIM Chapter 10 and then the CMS-855 for completeness.

Step #3: Once the MAC determines that the CMS-855 is accurate based on enrollment criteria, the MAC will provide its recommendation to the SA and the AO (if applicable) and include the CMS-855 with the package. The MAC will determine the AO based on the information listed in Section D of the CMS-855A (Section E for CMS-855B).

Step #4: Once the SA (or AO for deemed facilities) receives the MAC recommendation, the SA or AO will review the package within 30 business days to determine if the request is an administrative change.

Each of these requests requires that the CMS-855A or CMS-855B is submitted to the MAC (with the exception of temporary closures and ESRD removal and change in modalities and services). Additional documentation for each administrative change is further outlined in the applicable by-provider/supplier addendums, as transitioned.

Step #5: Upon initial review, the SA or AO (if applicable) will either:

> **5a) Schedule a survey** to determine if the administrative change meets the requirements (Follow Steps #6A to end);
>
> **5b) Proceed with a recommendation of approval without a survey** (Follow Steps #6Bto end); or
>
> **5c) Recommend denial** of the administrative change (Step #6C only). **AOs must copy the CMS Location and SAs in their recommendation for denial directly to**

the MACs.
Denials recommended by either the SA or AO would generally be based on non-compliance with the Medicare conditions or issues related to licensure. (See Step #6C for additional information)

NOTE: If the MAC receives the CMS-855 application from the provider/supplier but has not received the SA's or AO's recommendation within 90 business days, the MAC will process the application and make a recommendation of approval or denial to the SA. While the MAC has received the CMS-855 from the provider/supplier directly or via the SA (Step #1), it will still be required to wait for the SA or AO approval or denial before processing any of these administrative changes, unless it is a name change or address change directly reported to the MAC.

Step #6A: **If the SA or AO concludes that circumstances DO warrant a survey**, the SA or AO (if applicable) will schedule an onsite survey and will make no further findings until a survey has been completed (Follow Steps #6A to end).

NOTE: SA surveys are scheduled based on the Mission & Priority Document. For AO surveys, the AOs are not held to the MPD requirements. However, **the AO must communicate *intent* to survey to the SA within 30 business days.** ***Note: In the event the SA or AO conducts an administrative change survey in conjunction with a recertification/reaccreditation survey, the SA/AO must notify the MAC via the process below regarding the administrative change. Approvals/denials of recertification/reaccreditation surveys will remain unchanged from current processes (e.g. notification to the CMS Locations).***

Step #6B: **If the SA or AO concludes that circumstances DO NOT warrant a survey but recommends approval**, the SA or AO will send their recommendation and any relevant information provided by the provider/supplier to the MAC via the CMS-1539 (or comparable form for AOs) within 30 business days. For deemed facilities, the AO must copy the SA on communications to the MAC. (Follow Steps #6B to end). The CMS Locations retain the authority to review AO certification recommendations at any time.

Step #6C: If the SA or AO recommends denial, the SA or AO will provide the MAC with the denial recommendation. The MAC will process the application denial in accordance with PIM guidance. For deemed facilities, the AO must copy the SA and CMS Location on communications to the MAC. The CMS Locations retain the authority to review AO certification recommendations at any time.

NOTE: If the administrative change was not approved for reasons related to lack of documentation, findings of non-compliance, etc., the SA or AO will follow up with the MAC, who will follow PIM procedures regarding denials.

A denial of an administrative change may be a denial of a certification action. For example, if the SA/AO recommends denial of the relocation because the provider/supplier is not serving the same community/population, it would be considered a cessation of business and would be processed as a voluntary termination.
No changes are required in the national database system until the voluntary termination has been processed.

(Steps #7 through end do not apply to denials)

Step #7: The SA will send the recommendation of approval to the MAC via the CMS-1539. For deemed facilities, the AO will send the recommendation of approval to the MAC via a comparable CMS-1539 form, copying the SA.

Once the MAC receives the recommendation of approval from the SA or AO (if applicable), the MAC will review the documentation in accordance with the requirements in the PIM.

Step #8: The MAC will notify the CPI/PEOG, who will update the national database system. The CPI/PEOG should enter all applicable information into the national survey data system simultaneously with the release of the approval letter. (See Part II, Section V- National Database Updates, CMS Certification Numbers (CCNs) & Effective Dates)

Step #9: The MAC will then send the provider/supplier the approval letter and forward a copy of the approval letter to the appropriate SA, AO if applicable, and CPI/PEOG. The approval letter to the provider/supplier must include the assigned Federal branch ID number if this is part of a Branch or Extension site, which the MAC will obtain from CPI/PEOG.

Section III- Determining Survey Needs (SA and AO (if applicable) Responsibility

Upon receipt of a provider's/supplier's request of an administrative change, the SA and AO (if applicable) will review and make a determination on whether or not a survey is required prior to sending any information or recommendations to approve the transaction to the MAC (see step- by-step process).

The SA or AO (if applicable) may consider at a minimum the following for determining a survey based on the requested change:

- Is the change within the same geographical area?
- Does the change impact beneficiaries?
- Is the change purely administrative, such as name change?
- If adding or removing locations or there is a cessation of business, what is the impact to beneficiaries?
- Are there new services being provided?
- Is the same staff used?
- What is the facility's past compliance history?;
- Any open enforcement actions against the provider/supplier?
- Are the modalities appropriate for the needs of the patients it accepts for service?

NOTE: The SA and AO may have additional criteria for determining survey needs.

For U.S. Territories: The steps outlined under the processing section (Section II above) still apply, however the CMS Locations will be the responsible for processing administrative changes with the MAC and CPI/PEOG in lieu of the SAs. If the provider/supplier is deemed by a CMS- approved AO, the AO will coordinate with the CMS Locations in lieu of the SAs.

For Accrediting Organizations: For providers and supplier which are deemed (Hospitals, CAHs*, ESRD facilities, HHAs, Hospices, RHCs*, OPTs, ASCs) by a CMS-approved

accrediting organization (AO), the provider/supplier will request an administrative change following the same process as outlined above.

The MAC will include the AO on recommendation communications to the SA. The AO will communicate recommendations for approval or denial directly with the MAC; however, they will **copy the SA on all communications. For recommendations of denials, the AO must copy the CMS Location on all communications. It is the responsibility of the SAs to update the national database system as applicable/needed for deemed activities once copied by the AO.** The SA may contact the CMS Locations in the event there is any uncertainty on an AO's recommendation of approval or denial. **The CMS Locations retain the authority to review AO certification recommendations at any time.**

We are also requesting that all AOs use a comparable form (per 488.5(a)(4)) to the SA Form CMS-1539 for communications to the MAC, SA, and CMS Locations for a consistent and streamlined process. CMS has developed a template comparable form we encourage the AOs to use.

AOs may have additional requirements (exceeding SA processes) in which they determine survey needs. It is the responsibility of the AO to communicate to the SA, copying the CMS Location. **The AO must communicate *intent* to survey to the SA and CMS Location within 30 business days per the step-by-step instructions.**

SECTION V- National Database Updates, CMS Certification Numbers (CCNs) & Effective Dates

For most administrative changes such as name/ownership changes that are not a CHOW, the CCN will remain under the existing/approved CCN. No change is required by CMS CPI/PEOG. In most circumstances, if a facility relocates within the same state, CMS will determine if the facility will retain its Medicare agreement and CCN. **CPI/PEOG is responsible for updating the following fields in the national database: 1) Initial Certification Date; 2) Termination Date; 3) Action Code; 4) Determination Approval Date; 5) Receipt Date; and 6) CCN's and Branch IDs (and NPI for ASCs and PXR suppliers)**. NOTE: For CHOWs as outlined in Part I of this SOP, CPI/PEOG will be responsible for also entering the CHOW Effective Date into the national database system.

The SAs will be responsible for updating the national database for all associated other information, including updates for deemed recommendations which the SA is copied on.

Important Nuances for National Database Entries and CCN issuance:

CPI/PEOG will be assigning the CCN. The CCNs will remain unchanged for administrative changes, except in the following circumstances listed below. Additionally, the below captures general information on who (CPI/PEOG or SAs) will update the national database system.

Name & Address Change (Not Relocation): The SA will update the national database system after receiving the MAC's approval. This would include updating the legal entity/name and a change in the DBA. Note: The SA will be responsible for updating any

licensure requirements as needed.

Adding/Removing Sites, Services, or Locations:

- For CORF, HHA, Hospital, Hospice, and OPTs: The location information, Branch IDs, and CCNs will be issued by CPI/PEOG. CPI/PEOG will update the national database system. For HHAs and OPTs, CPI/PEOG will be responsible for also issuing or removing the branch ID or extension site identifier. Do not remove/terminate the parent CCN in a branch removal.
- For ESRD expansions/removal and change in modalities/services, the SA will be responsible for updating the national database system.

Change in Location/Relocation: The SA will update the national database system.

Cessation of Business: CPI/PEOG will update the national database system. The CCN will be terminated along with the provider agreement. The MAC will first attempt to contact the owner to ensure that the cessation of business is not due to a change in location in which the provider has failed to notify the SA and MAC via CMS Form 855.

- **NOTE:** A temporarily closed facility may not retain its Medicare participation indefinitely. At the time of the temporary closure, the facility provides a projected date for resumption of services. The projected period of closure must be consistent with the repairs or renovation required. Depending on the duration, closure may be viewed as a cessation of business (voluntary termination of the Medicare CCN). The facility may be asked to submit periodic progress reports to the SA as to whether the projected re- opening remains the same. The SA will make these determinations in consultation with the CMS Location and notify the MAC.

Temporary Closure: No changes are required for temporary closures.

Please refer to the applicable by-provider/supplier addendums based on transition phases.

Effective Dates for Extension Locations, Additional Sites, and Change in Address (Not Relocation):

- Letters of approval must include the approval decision for the added practice (extension)location and the date that the SA/AO determined the added practice location met all appropriate CoPs. The effective date of coverage for services provided from the extension location is the date the SA/AO determines that the extension location meets all Federal requirements. This date will be included in the CMS notice letter sent by the MAC.
- The organization should not begin providing services at the newly added practice location until it receives a CMS notice from the MAC with an approval or denial of the new location.
- Reasons for denial if the request was denied and date of determination.

Part III –Initial Certification and Enrollment

Section I- General Information

SAs (or AOs as applicable) perform initial surveys certification of providers and certain suppliers, with the exception of FQHCs, which self-attest to being compliant. This part of the SOP outlines the roles and responsibilities for completing the initial certification activities for providers and certain suppliers.

NOTE: Transition of initial certification/enrollment for FQHC has been implemented. Please refer to the FQHC Transition SOP.

Section II- Overview Initial Certification

Initial certifications of providers or suppliers involve several steps, including enrollment and being surveyed to confirm their compliance and eligibility to participate in the Medicare program. Only CMS makes the determination to approve or deny a provider or for participation in the Medicare program. The SA transmittal of its findings is a recommendation for the certification action. The SA certification is used as the primary item of evidence to support decisions to approve or deny Medicare provider participation or coverage of provider or supplier services.

The SA reviews the appropriate provider documents (CMS-855A or CMS-855B; written recommendation; state licensure information, etc.) to distill essential information from the survey report for input into the national data system. Before an agreement is executed with a provider to participate in the Medicare program, they must submit evidence of successful electronic submission of the Form HHS-690 through the Office of Civil Rights (OCR) portal before an initial survey may be conducted. OCR conducts necessary investigations and makes determinations related to compliance with their requirements.

The SA completes all pertinent documentation relating to certification actions for each provider/supplier or action category and updates the national database system. The SA will forward their certification to the MAC no later than 45 calendar days after the initial certification survey.

U.S. Territories: For U.S. territories, the steps outlined under the processing section III still apply; however, the CMS Locations will be the responsible for processing initial certification actions with the MAC and CPI/PEOG in lieu of the SAs. If the provider/supplier is seeking deemed status by a CMS-approved AO, the AO will coordinate with the CMS Locations in lieu of the SAs.

For Accrediting Organizations: For providers and suppliers which are seeking deemed status through a CMS-approved accrediting organization (AO), the provider/supplier must still submit their CMS-855 and be processed through the general enrollment requirements (as outlined in Part III, Section III), however, the AO (not the SA) will conduct the initial survey. An AO may not conduct an initial certification survey of a prospective provider or supplier for Medicare certification purposes until the MAC has completed its initial review

of the enrollment application and has made a recommendation for approval.

For providers and suppliers seeking deemed status who are new to the Medicare program and undergoing initial enrollment, CMS recommends that the provider/supplier annotate "yes" under accredited on the CMS-855 and state in the comments section that the provider/supplier is seeking deemed status and pending an initial survey by the AO (including the name of the AO). This will ensure during the MAC can easily identify the AO during the initial review of the CMS-855 and communicate with the SA and AO, while recognizing that accreditation would not be finalized until after the initial survey. An AO must wait until the MAC has made its recommendation before it conducts an initial certification survey. CMS requires AOs with CMS-approved programs to employ a survey process that is comparable to the SAs.

For certification purposes, CMS considers only accreditation under a CMS-approved Medicare accreditation program where the AO has recommended deemed status of a provider/supplier after the initial survey has been completed. The SAs will be responsible for entering information into Deemed tab within the certification kit in the national survey data system for those initial applicants that are seeking deemed status prior to the AO survey on the basis of accreditation under a CMS-approved Medicare accreditation program and finalize the Deemed tab information upon completion of the survey. While AOs are not required to complete a comparable CMS-1539 for initial certifications, we recommend that the AO consider including the comparable CMS-1539 in their communication to the SA. Ultimately, the SA is responsible for completing the CMS-1539 form when submitting the final determination recommendation to the MAC, for deemed programs. AOs must continue to include any existing letters/notifications and information communicating their recommendations.

Section III- General Processing for All Providers/Suppliers (except for FQHCs)

Step #1: When an entity seeks to participate in Medicare, it must first complete and submit an enrollment application. Information on enrollment as well as applicable forms and instructions may be found at http://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/index.html. Entities subject to survey and certification file either a CMS Form 855A -- Medicare Enrollment Application for Institutional Providers, or a CMS Form 855B--Medicare Enrollment Application for Clinics, Group Practices, and Certain Other Suppliers.

Medicare Part A providers will be required to sign an attestation of their compliance with all applicable civil rights laws enforced by the HHS Office of Civil Rights (OCR). This attestation is referred to as an "Assurance of Compliance" (form HHS-690), and it can be found on the HHS website. New applicants will be responsible for submitting this attestation electronically to OCR via OCR's online Assurance of Compliance portal at https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf. They must submit evidence of successful electronic submission of the attestation (Form HHS-690) through the OCR portal before an initial survey may be conducted. SAs must include this link with their initial certification packages.

NOTE: If the prospective provider/supplier is seeking deemed status through a CMS-approved AO, it must still contact the SA for Medicare and/or Medicaid certification materials for their provider/supplier type.

Step #2: Once a prospective provider/supplier has submitted the initial enrollment application to the MAC, the MAC will review for enrollment.
Prospective providers and suppliers should be aware that the initial review of the Form CMS- 855A or Form CMS-855B by the MAC and its recommendation for approval must occur before the on-site initial certification survey is conducted.

Step #3: When the MAC completes its review of the application, it either:

1) sends the SA and AO (if applicable) its recommendation via email (Step #4A) (including recommendations of approval for prospective providers/suppliers seeking deemed status);
or,
2) denies the application based on enrollment criteria and notifies the applicant (Step#4B).

Step #4A: **If the MAC recommends approval,** the SA or AO (if applicable) receives the Form CMS-855A or Form CMS-855B along with the approval recommendation from the MAC. The SA will prepare the initial survey kit of the provider/supplier in the national database system (including for those providers/suppliers seeking deemed status). **NOTE:** The AO may not survey prior to receiving approval from the SA (See Part III, Section IV below).

Step #4B: If the MAC denies the application, based on enrollment criteria, the MAC will notify the provider/supplier in accordance with the PIM.

Step #5: If the SA and AO (if applicable) receives the MAC recommendation for approval per step #4A, **the SA (or AO if applicable) surveys** the prospective provider/supplier and either:

1) Certifies or recommends Medicare approval if it determines that the applicant is in compliance with all conditions of participation/coverage/certification or requirements, as applicable. The SA will notify the MAC of the applicant's recommendation for approval for participation in the Medicare program by sending the Form CMS-1539 via email within *45* business days after the date of the survey.

For prospective providers/suppliers who are seeking deemed status, the SA will receive the recommendation from the AO, review for concurrence with the findings, and process the initial certification kit and complete the CMS-1539 Form. The AO does not directly communicate with the MAC.

OR;

2) Determines the applicant is not in compliance with the conditions of participation, coverage, certification, or requirements, as applicable. If an initial denial is determined, the SA forwards the final determination recommendation for initial denials (including the AO's recommendation of denial of deemed status) to the MAC within *45* business days after the date of the survey via the CMS Form-1539 (Refer to note below- this may be after three full initial surveys- See SOM Chapter 2, Section 2005A).

The SA, including for deemed facilities, will annotate on the CMS-1539 whether this is the provider's 1st, 2nd or final attempt at survey for initial certification. If the SA (or AO) continues to find the applicant is not in compliance with the conditions of

participation/coverage/certification or requirements, the SA will send a CMS-1539 indicating the provider is not eligible to participate and annotate the corresponding reason.

Following the initial denial, the applicant may submit no more than two reapplications for certification in connection with the one enrollment application (for a total of 3 certification attempts); and no more than six months may have elapsed between the date of the first denial of certification and any subsequent surveys.

Deemed Note: For prospective providers/suppliers seeking deemed status and failure to comply with the requirements, the SA will receive the recommendation via the AO. The SA will complete the CMS-1539 for deemed providers who are not recommended for initial certification and send to the MAC as indicated above.

The SA populates all data in the initial certification kit in the national survey data system for both deemed and non-deemed facilities with the exception of any data fields they do not have permission to enter.

Step #6: Once the MAC receives the SAs recommendation (including the recommendations the AO provided for their respective deemed facility) via the CMS- 1539 for certification approval or denial, the MAC generates the appropriate notice for CPI/PEOG signature.

NOTE: The MAC will only take action to close the CMS-855 when the "Final Attempt" checkbox is selected. The MAC will follow the PIM guidance and only take final action to close the CMS-855 when the "Final Attempt" checkbox is selected on the CMS-1539.

Step #7: The CPI/PEOG will sign the provider or supplier agreement with an effective date and issue the CMS Certification Number (CCN). The MAC sends a copy of the applicant's approval letter (and signed agreement) to the provider/supplier and copies the SA and AO (if applicable). In the national database, CPI/PEOG will complete the effective date and CCN fields in the initial certification kit and upload.

SECTION IV- Survey Priorities & Accrediting Organizations

Reminder Scheduling Surveys: Initial certification survey scheduling will vary based on the provider/supplier type as outlined within the Mission and Priority Document (MPD). For MAC and CPI/PEOG awareness, there will be varying times based on the Tier levels for each provider/supplier type. The SA or AO (if applicable) must not perform a survey of an initial applicant until it has received notice from the MAC that the information provided on the enrollment application has been verified and that the MAC is recommending approval of the application.

For Accrediting Organizations: If the provider/supplier intends to be deemed, the SA does not conduct a survey to initially certify or recertify compliance with the applicable Medicare CoPs, CfCs, or requirements. Rather, such providers or suppliers are under the jurisdiction of the AO, not the SA. **The AO will recommend approval/denial of deemed status based on their initial survey findings to the SA, copying in the CMS Location.** An AO may not conduct an initial certification survey of a prospective provider or supplier for Medicare certification purposes until the MAC has completed its initial review of the enrollment application and has made a recommendation for approval to SA/AO.

The SA is responsible for updating the deemed certification kit in the national database system along with other required information. The CMS Locations retain the authority to review AO certification recommendations at any time.

SECTION V- CMS Certification Numbers (CCNs) & Effective Dates

CMS Certification Number (CCN) - General Guidance:

The CPI/PEOG will assign the CCN based on the provider/supplier-specific information included in the Addendums as the transition work proceeds.

The CCN for providers and suppliers paid under Medicare Part A has 6 digits. The first 2 digits identify the State in which the provider is located. The last 4 digits identify the type of facility. CMS PEOG will assign the CCN based on the existing guidance outlined in SOM Chapter 2, Section 2779A1 – CCN for Medicare Providers. CCNs are issued based on the last issued CCN in the sequence.

Effective Date: In accordance with 42 CFR 489.13, the effective date of participation in the Medicare program, i.e., the effective date indicated on the provider or supplier agreement issued by the CPI/PEOG via the MAC, may not be earlier than the date on which CMS determines that the provider or supplier meets all applicable federal requirements.

Part IV –Appeals and Reconsiderations

Reminder: All enforcement action processes remain unchanged and are the responsibility of the CMS Locations and the SA.

Appeals and reconsiderations for the purposes of this SOP may be based on two separate parts, either a determination that is based on the provider's/supplier's non-compliance with the Conditions for Participation (CoPs), Conditions for Coverage (CfCs) or requirements for LTC facilities; or 2) based on enrollment determinations. This section applies to both CHOWs and Administrative changes.

Procedures/Guidance for Termination of Provider Agreement upon Revocation:
Revocation of a provider's enrollment billing privileges in the Medicare program automatically results in termination of the associated provider agreement. In the event the MAC revokes the provider/supplier based on enrollment criteria, the MAC will notify CPI/PEOG if the revocation determination is not appealed within 150 business days from the date of the notification.
CPI/PEOG will terminate the Provider Agreement in the national database system.

The MAC will be responsible for issuing one letter to the provider/supplier noting the reconsideration/appeal rights for the Provider Agreement terminations and separately Provider Enrollment revocations. Formal written notice must include the right for reconsiderations and/or appeal and is issued by the MAC in accordance with the PIM

The following information is included in the formal notice:

- The date of the notice;
- The decision and reason for it (cite provisions of the law or regulations not

met);this may be reflected in two parts:
    - Specific information related to MAC revocation due to enrollment, and/or;
    - Specific information related to revocation based on certification (e.g. Provider Agreement terminations).
- The right to request participation in the future; and
- The procedures to follow for requesting a reconsideration and hearing before an administrative law judge (ALJ).

NOTE: This guidance supersedes previously issued S&C: 12-16-ALL.

Initial Denial of Participation and Enrollment: An initial denial is made when, after evaluating the evidence the SA certifies that the requirements of law and regulation (conditions of participation (CoPs)) are not met (including those recommendations/findings provided from the AO to the SA). The SA forwards recommendations for initial denials to the MAC within *45* business days after the date of survey via the CMS Form-1539. **The MAC will follow the processes as outlined in the PIM for sending one consolidated letter to the provider/supplier.**

Reasonable Assurance: The CMS SOG Locations will continue to process all enforcement activities, including reasonable assurance determinations for terminated providers/suppliers who wish to reenter the Medicare program.

A Medicare provider terminated under 42 CFR 489.53 and reinstated under 42 CFR 489.57 is required to operate for a certain period of time without recurrence of the deficiencies, which were the basis for the termination. The reasonable assurance concept also applies to terminated Medicare suppliers such as ASCs (42 CFR 416.35(e)), FQHCs (42 CFR 405.2440), and ESRD facilities (42 CFR 405.2180(c)). The length of this "reasonable assurance" period is determined by the CMS SOG Locations after an evaluation of the provider or supplier's previous compliance history. The reasonable assurance decision is an administrative action (not an initial determination) and is not subject to the appeals process at 42 CFR Part 498.3(d)(5).

Part V –Important Reminders & Resources

Use of the CMS Form 2007 will become limited. The SAs will communicate with the MACs using the Form CMS 1539.

Additional Resources

- Enrollment aspects of the CHOW process are addressed in the Medicare Program Integrity Manual, Chapters 10, 15.

- The Medicare Financial Management Manual, CMS Publication 100.06, Chapters 3 and4, address overpayment and other financial issues related to acquisitions and/or CHOWs of Medicare-participating providers.

- The Provider Reimbursement Manual, CMS Publication 15-1 and 15-2, at section § 4502.B explains when a "CHOW" has occurred for Medicare reimbursement purposes.

Attachment 2:
SKILLED NURSING FACILITIES ADDENDUM
Transition Complete- Transition Occurred on January 3, 2022

Purpose: The intent behind the Standard Operating Procedure (SOP) is to provide direction to the Survey Operations Group (SOG) (later referred to as CMS Locations), State Survey Agencies (SAs), and the Center for Program Integrity (CPI)/Provider Enrollment Oversight Group (PEOG) and the Medicare Administrative Contractors (MAC) as it relates to the processing of changes of ownership (CHOWs), administrative changes (name, address, branch locations, additional services, relocations, etc.), and initial surveys and enrollment.

Scope: The SOP covers multiple parts to include 1) CHOWs; 2) Administrative Changes and 3) Initial Certification and Enrollment. The SAs, CPI/PEOG, and the MACs will follow the general guidance provided in the main SOP, however **this Skilled Nursing Facilities (SNFs) Addendum covers provider differences, nuances, and areas specific to Long-Term Care Facilities. NOTE: Only SNFs are part of the simplified the enrollment and certification activities with the MAC and CPI/PEOG.**

NOTE: For SNFs, there are no CMS-approved Accrediting Organizations (AOs). Deeming authority for SNFs is not available. No AO involvement.

General Information & Background

Definitions (42 CFR 488.301):

- **Dually Participating Facility** means a facility that has a provider agreement in both the Medicare and Medicaid programs.

- **Facility** means a skilled nursing facility or nursing facility, or a distinct part of a skilled nursing facility or nursing facility, in accordance with 42 CFR 483.5. (See §7008 for entities that qualify as skilled nursing facilities and nursing facilities.)

- **Nursing facility (NF)** means a Medicaid nursing facility.

- **Skilled nursing** facility (SNF) means a Medicare-certified nursing facility that has a Medicare provider agreement.

Participation & Survey/Certification Requirements:

The State (SA) has the responsibility for certifying a SNF's or NF's compliance or noncompliance, except in the case of State-operated facilities. However, the State's certification for a SNF is subject to CMS's approval. "Certification" of compliance means a determination made by SAs that providers and suppliers are in compliance with the applicable conditions of participation, conditions of coverage, conditions for certification, or requirements (42 CFR 488.1).

The following entities are responsible for surveying and certifying a SNF's or NF's compliance or noncompliance with Federal requirements:

- **State-Operated Skilled Nursing Facilities (SNFs) or Nursing Facilities (NFs) or State-Operated Dually Participating Facilities** - The State conducts the survey and certifies compliance or noncompliance and determines whether a facility will participate in the Medicare or Medicaid programs. Note: **There is no CPI/PEOG and MAC involvement for Medicaid-only (NF) participation**. In dually participating facilities, CPI/PEOG and the MAC will receive directions for processing certification actions by the SA, unless open enforcement activities exist.

- **Non-State Operated Skilled Nursing Facilities (SNFs)** - The State conducts the survey and certifies compliance or noncompliance. The SA will determine whether a facility is eligible to participate in the Medicare program and provide certification and enrollment recommendations to CPI/PEOG and the MAC.

- **Non-State Operated Nursing Facilities (NFs)** - The State conducts the survey and certifies compliance or noncompliance. The State's certification is final. **The State Medicaid Agency determines whether a facility is eligible to participate in the Medicaid program.** Note: **There is no CPI/PEOG and MAC involvement.**

- **Non-State Operated Dually Participating Facilities (Skilled Nursing Facilities/Nursing Facilities)** - The State conducts the survey and certifies compliance or noncompliance. The State's certification of compliance or noncompliance is communicated to the State Medicaid Agency for the nursing facility and to the CPI/PEOG and the MAC for the skilled nursing facility.

CMS Certification Numbers for SNFs:

Use the following CCN ranges for the facility types indicated:

5000-6499	Skilled Nursing Facilities
6990-6999	Numbers Reserved (formerly Christian Science Sanatoria (Skilled Nursing Services)

PART I- Changes of Ownership (CHOWs)

Skilled nursing facilities (SNFs) are subject to the CHOW rules as noted in 42 CFR 489.2(b)(2). See Part I of the SOP for a general overview of CHOWs.

CHOWs - Skilled Nursing Facilities (SNF)- Long- Term Care:

- If a buyer/new owner does not reject automatic assignment, Part I, Section I of the main SOP would be followed, however the SA's and MACs must review the specific

information below related to supporting documentation prior to finalizing a CHOW for a SNF.

- If a buyer/new owner rejects automatic assignment, it is not a CHOW. It is an initial certification requiring initial enrollment for the new owner. In that case, Part I, Section II of the SOP would be followed.

- SNF CHOWs often take the form of a new operator. The documentation of the CHOW transaction is the operating transfer agreement from the old operator to the new operator. This is still a CHOW, even though the operator does not own the building, it is still the entity with legal responsibility for the operation of the nursing home provider itself.

- If the State is concerned that a CHOW, management firm, administrator, or Director of Nursing may have caused a decline in the quality of care or services furnished by a skilled nursing facility or nursing facility, it may conduct a standard or abbreviated standard survey within 60 days of the change. The SA will make the determination once it receives the CHOW package from the MAC for the initial review and recommendation of approval or denial.

- The MAC may obtain only part of these documents during the initial request, however the SA may need to follow up with the provider to obtain the remaining documentation. The final CHOW package supporting documentation should include the documents listed below:
    - The CMS-855 provided from the MAC
    - The provider agreement (CMS-1561);
    - CMS-671 (LTC Facility Application for Medicare/Medicaid)
    - CMS-672 Resident Census
    - The Office of Civil Rights (OCR) attestation confirmation (Providers must complete online at https://ocrportal.hhs.gov/ocr/aoc/instruction.jsf);
    - SA completed CMS-1539 and written recommendation for approval of the CHOW;
    - Verification that the Nurse Aide Training & Competency Evaluation Program (NATCEP) is being carried out by facility;
        - **NOTE:** The SA is required to have their process for their state's NATCEP program, this may include but not be limited to, review of the facility curriculum, qualifications of instructors, etc.
    - A copy of transfer agreement(s) with acute care hospital(s). The new owner must be a party to the transfer agreement, not the old owner.
        - **NOTE**: Per the regulations at 483.70(j)(2), the facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible.
        - There may be cases in which the SNF provides evidence that they attempted to obtain a transfer agreement but was unable to do so. The SA will determine if adequate information was obtained support approval of the CHOW without a formal transfer agreement.

- Supporting Documentation to be submitted to the MAC by the SA must include:
    - CMS-855A;
    - Recommendation of Approval CMS-855A BUYER Medicare Enrollment Application;
    - CMS-1539 C&T: SA Recommendation of approval prepared and submitted to the MAC with entire application (all documents listed above)

Distinct Part SNF's and CHOWs: Understanding the term "distinct part" SNF or NF is important. This refers to a portion of an institution or institutional complex (e.g., a nursing home or hospital) that is certified to provide SNF services. The distinct part can be a wing, separate building, a floor, a hallway, or one side of a corridor. The beds in the certified distinct part area must be physically separate from (that is, not commingled with) the beds of the institution or institutional complex in which it is located.
A composite distinct part is a distinct part consisting of two or more non-contiguous components that are not located within the same campus, as defined in §413.65(a)(2).

A distinct part SNF could occur in situations in which a hospital has a distinct part SNF. Generally, this is seen where a hospital that has a distinct-part SNF and either the hospital, the SNF, or both undergo a change in owners and the new owners accept assignment of existing Medicare agreements. In this case, if a change in ownership situation results in the hospital and the distinct-part SNF having different owners, and **the existing SNF Medicare agreement continues**, the SNF is no longer certified as a distinct-part SNF, but **its CCN would remain unchanged**. The loss of distinct-part status would be noted in the national survey data system.

The SA will be responsible for notifying the MACs if a distinct part situation occurred during a CHOW and there was a loss of distinct part status. If two or more institutions (each with a distinct part SNF or NF) undergo a change of ownership, CMS must approve the existing SNFs or NFs as meeting the requirements before they are considered a composite distinct part of a single institution. In making such a determination, CMS considers whether its approval or disapproval of a composite distinct part promotes the effective and efficient use of public monies without sacrificing the quality of care. If there is a change of ownership of a composite distinct part SNF or NF, the assignment of the provider agreement to the new owner will apply to all of the approved locations that comprise the composite distinct part SNF or NF.

Part II –Administrative Changes

Many enrollment certification actions are not CHOWs. These situations are generally when a provider/supplier changes names not due to a CHOW, or there is an administrative update to the provider agreement.

Administrative Changes - Skilled Nursing Facilities (SNF)- Long- Term Care:

In accordance with the steps under Part II – Administrative Changes of the main SOP, the SA will be responsible for confirming the type of administrative request and providing the recommendation for approval to the MAC once a survey has or has not been conducted based on

the criteria outlined. In rare occasions, administrative changes occur in SNFs which are not considered CHOWs. These generally are:

- **Address Change (Not Relocation):** Ordinarily an on-site survey is not necessary for a change of address unless the location is outside the approved geographic area.

- **Name Changes**: Name changes of an organization may occur that are not as a result of a CHOW, but rather changes of Owners (see Part I, Section III.B.). These may be changes to the owner's information or the organization name as a whole. SAs must receive the CMS-855A Change of Information (CHOI) recommendation of approval from the MAC before the SA may change the facility name in the National Database; CMS-1539 C&T: SA Recommendation of approval prepared and submitted to the MAC with copy of the CMS-855A CHOI.

- **Change in Location/Relocation:** A change in location or relocation is outside of the primary approved site or change in location outside of the existing geographical area is generally considered a relocation of a provider/supplier. A relocation request must also ensure that patients will continue to receive uninterrupted service during the relocation. A relocation may or may not need a survey. **Prior to approval of a SNF relocation, the SA performs a Life Safety Code Survey of the new building or location and requires the CMS-855A to be approved before the facility may relocate/transfer residents to the new location.**

  As part of the steps outlined in Part IV of the main SOP, note that if the SA recommends denying the relocation of a main site, this is considered a termination.

  In rare occasions, relocations may occur in SNFs which are not considered CHOWs. Relocations in SNFs are generally only the result of:
  1) Enforcement- The facility is being terminated and must transfer residents (involuntary termination);
  2) Emergencies- Relocating residents based on temporary closure due to an emergency.

  In either case, the SA will follow the existing processes and termination/enforcement will continue to be processed by the SA and applicable CMS SOG Location per SOM Chapter 7, Section 7552 - Transfer of Residents and Transfer of Residents with Closure of Facility.

- **Distinct Part**- Refer to above explanation of distinct part. **A distinct part is not an administrative change, but may be seen as part of the SA submission of a CMS-1539. One CCN is assigned and only one Form CMS-1539 prepared for the SNF/NF with a SNF or NF distinct part; and with a NF distinct part.**

In the event the SNF decides to voluntarily terminate, the SA, CPI/PEOG and the MACs will follow the procedures outlined in the Voluntary Termination SOP.

Part III –Initial Certification and Enrollment

Initial Enrollment for SNFs will follow Part IV, Section III of the SOP. For SNFs specifically, the SA determines whether a prospective provider is in substantial compliance with the nursing home participation requirements upon initial survey of the facility. The SA also ensures that part of the initial survey includes the LSC survey. The initial survey cannot take place until the SA receives the Form CMS-855A along with the approval recommendation from the MAC per Part IV, Section III of the SOP.

The SA will review:

- All documents listed above for a CHOW are also collected from the provider and required for an Initial Certification Application;
- Some SAs will also request a Floor Plan with all resident room numbers clearly indicated;
- Some SAs will also require a bed listing form (generally a state document);
- The CMS-855A recommendation of approval from the MAC before the SA can conduct the initial certification survey, and subsequently, the facility must have achieved compliance with the requirements for participation in the Medicare program demonstrated through the survey process.

After the initial survey is completed by the SA, the following will apply:

For APPROVALS: If the facility is in substantial compliance, the State certifies and recommends approval to the MAC and/or State Medicaid Agency. The MAC will notify PEOG who will take the required actions to finalize the HHS agreement with the facility.

NOTE: In the event an initial survey results in standard-level/minimal harm deficiencies, the SA will request a plan of correction (PoC). Only once the SA receives an acceptable PoC, will the SA make its determination of substantial compliance and send their recommendation to the MAC.

CMS-1539 C&T within initial certification survey kit: SA Recommendation of approval prepared and submitted to the MAC with entire application (all documents listed above) by SA.

For DENIALS: If the facility is not in compliance, the SA will recommend denial to the MAC, CMS Location and/or State Medicaid Agency, and follow the existing SOM guidance and main SOP. For additional information, SAs will refer to existing guidance under 42 CFR 431.153 and 42 CFR 498.3(b) and SOM Chapter 2 and 7, §2005 and §7203.

Part IV –Important Reminders & Resources

Important Reminders Resources

- Some providers such as OPT/OSPs might provide services in a SNF and a CORF and be established on the premises of another health entity even though the other entity is currently approved under Medicare as a provider or supplier of services. For example, a

SNF owner might rent space within the SNF to the CORF or OPT/OSP. **These are considered separate provider/supplier actions and are not applicable to these certification transition actions specific to SNFs.**

Additional Resources

- CHOW, Administrative Changes; Relocations & Initials- General SOP
- SOM Chapter 2
- SOM Chapter 7
- SOM Appendix P & PP (Surveyor Guidance)

Attachment 3:
ASCs, CMHCs, CORF, FQHC, HHA, OPT & PXR ADDENDUM

Transition Complete - Transition Occurred on May 30, 2022

Purpose: The intent behind the Standard Operating Procedure (SOP) is to provide direction to the Survey Operations Group (SOG) (later referred to as CMS Locations), State Survey Agencies (SAs), Accrediting Organizations (AOs), and the Center for Program Integrity (CPI)/Provider Enrollment Oversight Group (PEOG) and the Medicare Administrative Contractors (MAC) as it relates to the processing of changes of ownership (CHOWs), administrative changes (name, address, branch locations, additional services, relocations, etc.), and initial surveys and enrollment.

Scope: The SOP covers multiple parts to include 1) CHOWs; 2) Administrative Changes; 3) Initial Certification and Enrollment. The SAs, CPI/PEOG, and the MACs will follow the general guidance provided in the SOP, however **this Addendum also covers provider/supplier differences, nuances, and areas specific to Ambulatory Surgical Centers (ASCs), Community Mental Health Centers (CMHCs); Comprehensive Outpatient Rehabilitation Facilities (CORFs); Federally Qualified Health Centers (FQHCs); Home Health Agencies (HHA), Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP) and Portable X-Ray (PXR) Providers.**

For FQHCs, CMS has transitioned initial enrollment activities. Please refer to https://www.cms.gov/files/document/admin-info-21-06-all.pdf

General Information & Background

Definitions:

In Medicare, the general distinction between providers and suppliers is that providers are parties who care for patients awaiting, receiving, or recuperating from treatment by intervening practitioners. In Medicare, the term "suppliers" includes those who furnish goods and services used in care and treatment.

- **Ambulatory Surgical Centers (ASCs):** Section 1832(a)(2)(F) of the Social Security Act (the Act) provides that, as an adjunct to outpatient surgical services, ASC facility services can be paid under Part B of the Medicare program. Though it is a supplier, an ASC must be certified and approved to enter into a written agreement with CMS. The Conditions for Coverage of ASC services are found in 42 CFR part 416. An ASC may be either hospital-operated or independent. The hospital-operated ASC must be a separately identified entity. It must be physically and administratively distinct from other operations of the hospital and be able to identify its costs separately from other hospital costs.

- **Community Mental Health Centers (CMHCs):** Medicare defines CMHCs as outpatient organizations that provide partial hospitalization services to Medicare beneficiaries. A CMHC, defined in §410.2, is "an entity that- (1) Provides outpatient

services, including specialized outpatient services for children, the elderly, individuals who are chronically mentally ill, and clients of its mental health service area who have been discharged from inpatient treatment at a mental health facility; (2) Provides 24-hour-a-day emergency care services; (3) Provides day treatment or other partial hospitalization services, or psychosocial rehabilitation services; (4) Provides screening for patients being considered for admission to State mental health facilities to determine the appropriateness of this admission; (5) Meets applicable licensing or certification requirements for CMHCs in the State in which it is located; and (6) Provides at least 40 percent of its services to individuals who are not eligible for benefits under title XVIII of the Social Security Act."

- **Comprehensive Outpatient Rehabilitation Facilities (CORFs):** A CORF is a facility established and operated at a single fixed location exclusively for the purpose of providing diagnostic, therapeutic, and restorative services to outpatients by or under the supervision of a physician. The CORF provides a broad array of services that must include, at a minimum, the following three core services: physician services, physical therapy services and social work or psychological services. (Section 1861(cc) of the Act; 42 CFR 485.51)

- **Federally Qualified Health Centers (FQHCs):** Social Security Act (SSA) § 1861(aa) provides additional Medicare payments to FQHCs. FQHCs are safety net providers that provide services typically given in an outpatient clinic. Medicare pays FQHCs based on the FQHC Prospective Payment System (PPS) for medically necessary primary health services and qualified preventive health services given by an FQHC practitioner. An FQHC is defined in 42 CFR 405.2401(b).

- **Home Health Agencies (HHA):** A HHA is an agency or organization which is primarily engaged in providing skilled nursing services and other therapeutic services and meets the CoPs in the interest of the health and safety of individuals who are furnished services by the HHA; and meets additional requirements as the Secretary finds necessary for the effective and efficient operation of the program, among other requirements. For purposes of Part A home health services under Title XVIII of the Social Security Act, the term "home health agency" does not include any agency or organization which is primarily for the care and treatment of mental diseases. (See section 1861(o) and 1891 of the Act and 42 CFR part 484).

- **Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP):** There are three types of organizations that may qualify as providers of outpatient physical therapy and speech-language pathology services under 42 CFR Part 485, Subpart H: clinics, public health clinics, and rehabilitation agencies. However, rehabilitation agencies are the only organizations that are currently enrolled as a Medicare provider with a CMS Certification Number (CCN).

- **Portable X-Ray (PXR):** The statutory authority for coverage of suppliers of portable x-ray services is found in §1861(s)(3) of the Act. A PXR is a Medicare-recognized supplier and its equipment and personnel must be licensed or registered in accordance with all applicable Federal, State and local laws, including licenses and registration permits to

confirm their validity and currency. (42 CFR 486.100) PXR suppliers must provide their services in conformity with Federal, State, and local laws relating to safety standards, including the requirement that the facilities comply with Food and Drug Administration (FDA) performance standards for diagnostic x-ray systems at 21 CFR Chapter I, Subchapter J, Radiological Health.

Participation & Survey/Certification Requirements:

For all of these providers/suppliers, the State (SA) has the responsibility for certifying compliance or noncompliance. The SA schedules survey activities based on the Mission & Priority Document (MPD). In addition, the below highlights specific nuances seen among these settings:

- **ASCs:** The State (SA) has the responsibility for certifying for compliance or noncompliance. The SA schedules survey activities based on the Mission & Priority Document (MPD). For Accrediting Organizations (AOs) with a CMS-approved program, the survey scheduling is not to exceed 36 months from the effective date of the last survey and based on the AOs scheduling for administrative changes.

- **CMHCs:** The State (SA) has the responsibility for certifying for compliance or noncompliance. The SA schedules survey activities based on the Mission & Priority Document (MPD).

- **Comprehensive Outpatient Rehabilitation Facilities (CORFs):** A CORF may be owned by, or affiliated with, a legal entity operating as another type of Medicare provider. A CORF may be established on the premises of another health entity even though the other entity is currently approved under Medicare as a provider or supplier of services. For example, a SNF owner may rent space within the SNF to the CORF. The CORF must be functionally and operationally independent from the SNF (see additional information under Part II of this addendum).

- **FQHCs:** This are considered a "self-attested" supplier which is subject to a filing procedure instead of a SA initial certification survey for enrollment as a Medicare-certified supplier. Under this procedure, the applicant must attest that it is and will remain in compliance with all applicable Medicare regulations. To attest to being in compliance, the facility must be open and operational when the attestation is signed. The SA does not survey to confirm the organization's compliance with Medicare's regulations. Refer to FQHC SOP.

- **Home Health Agencies (HHA):** It is permissible for an HHA to be located at a single site or have a parent site with services available at other approved locations, unless prohibited by State law or regulation. If there is more than one site, there must be a designated parent site with any other designated sites (branches) being part of that agency as described in more detail below. The parent, branch or subunit must be operational during normal business hours as defined by the parent or subunit. The following terms are defined in §484.2:

    - **Subdivision:** A subdivision is a component of a multi-function health agency,

such as a hospital-based HHA or the nursing division of a health department, which independently meets the CoPs for HHAs. A subdivision would need to meet all requirements for the initial survey including completing the CMS Form-855A and having this form verified by the assigned Medicare Administrative Contractor (MAC). A subdivision may have branch offices and, if so, is regarded as a parent agency.

- **Parent HHA:** The parent HHA is that part of the HHA that develops and maintains administrative control of all approved locations. The parent HHA is listed on the Medicare Enrollment Application (Form CMS -855A.) The parent HHA is responsible for all services provided at the parent and those provided at any of its approved branch locations. The parent HHA must also submit any relevant updates for all approved locations on the Form CMS-855A.

- **Branch Offices:** A branch office is a location or site from which an HHA provides services within a portion of the total geographic area served by the parent agency. The branch office is part of the HHA and is located sufficiently close to the parent agency so that it shares administration, supervision, and services with the parent agency on a daily basis. The branch office is not required to independently meet the CoPs as an HHA.

- **Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP):** An OPT may provide services away from the primary site or extension location(s), this is referred to as "off-premises activity" at other locations (also see Part II of this SOP). This is a service, not a separate provider or CCN. An OPT/OSP may consist of:

  - **Primary Sites:** A rehabilitation agency must provide services at its approved primary site (the site that was issued the CCN).
    Note: The organization may apply to CMS for approval of another location near the primary site for the purpose of providing additional access to care. These locations are known as "extension locations" and are defined in 42 CFR 485.703.

  - **Additional sites** of service must be approved by the CMS SOG location as extension locations. When the OPT provides services away from the primary site or extension location(s), this is referred to as "off-premises activity" at other locations.

  - **Extension Locations**- Only rehabilitation agencies are permitted to have extension locations. The clinics operated by physicians and public health clinics are not permitted extension locations.

- **Portable X-Ray (PXR):** PXR are generally stand-alone suppliers. They may or may not have mobile units. These suppliers are rare in certification actions.

NOTE: Only ASCs, HHAs and OPT/OSP may be deemed to meet Medicare requirements through a CMS-approved AOs. There are no deeming programs approved for the other providers/suppliers in this addendum.

General Guidance- CMS Certification Numbers (CCNs) & Effective Dates

The effective date for ASC's, CMHC's and FQHC's participation is the date CMS signs the provider or supplier agreement and determines that all requirements, are met. Use the following CCN ranges for the facility types indicated:

- **ASCs:** Suppliers, such as ASCs, that are paid by Part B carriers have a 10-digit alphanumeric CCN. The first 2 digits identify the State in which the supplier is located. (See list of State Codes under subsection SOM Chapter 2, Section 2779A1.) The third digit is an alpha character that identifies the type of facility (for ASC this is C). The remaining 7 digits are the unique facility identifier. CPI/PEOG will assign the CCN.

  For example: ASC 10C0001062

  If an entity owns/requests multiple surgical locations and wishes them to participate in Medicare as an ASC, each location must seek separate participation and demonstrate independent compliance with the ASC CfCs as the regulations do not permit configurations of multiple ASC locations under one Medicare agreement. ASCs may only have one surgical location per CMS Certification Number (CCN).

- **CMHCs**: 1400-1499 Continuation of Community Mental Health Centers (also CCN ranges 4600-4799 and 4900-4999)

- **Comprehensive Outpatient Rehabilitation Facilities (CORFs):** 3200-3299 Continuation of Comprehensive Outpatient Rehabilitation Facilities (also CCN ranges 4500-4599 and 4800-4899)

- **FQHCs**: 1000-1199 Federally Qualified Health Centers (also CCN range 1800-1989)

- **Home Health Agencies (HHA):** 3100-3199 Home Health Agencies (also CCN ranges 7000-8499 and 9000-9799) AND APPLICABLE BRANCH IDENTIFIER- See above

- **Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP):** 6500-6989 Outpatient Physical Therapy Services AND APPLICABLE EXTENSION LOCATION IDENTIFIER- See above

- **Portable X-Ray (PXR):** Suppliers, such as PXR, that are paid by Part B carriers have a 10-digit alphanumeric CCN. The first 2 digits identify the State in which the supplier is located. (See list of State Codes under subsection SOM Chapter 2, Section 2779A1.) The third digit is an alpha character that identifies the type of facility (for PXR this is X). The remaining 7 digits are the unique facility identifier. CPI/PEOG will assign the CCN.

  For example: Portable X-Ray 21X0009807

PART I- Changes of Ownership (CHOWs)

Regulations at 42 CFR 489.2 apply to the provider/suppliers transitioning with this segment (and CFR 405.2434 for FQHCs).

ASCs, CMHCs, CORFs, FQHCs, HHAs, OPT/OSP and PXRs will follow the CHOW process outlined in Part I of the general SOP and as applicable, the processing instructions depending on the new owner/buyer accepting or rejecting automatic assignment. For all provider/suppliers (except FQHCs), the SA will be responsible for updating the national database system once approved. For FQHCs, CPI/PEOG will be responsible for updating the national database system. Accrediting Organizations (AOs) will be copied on all ASC and HHA CHOWs.

The below highlights forms which are required specifically for these provider/suppliers as part of a CHOW Package. The MAC may obtain only part of these documents during the initial request, however the SA may need to follow up with the provider to obtain the remaining documentation. The final CHOW package supporting documentation should include the documents listed below:

ASCs:

- CMS 1539 - Certification & Transmittal;
- CMS 855B - Enrollment Application; Legal Documentation of CHOW;
- CMS 377 - ASC Request for Certification in the Medicare Program;
- CMS 370 - ASC Benefits Agreement

CMHCs:

- CMS 1539 - Certification & Transmittal;
- CMS 855A - Enrollment Application;
- Legal Documentation of CHOW.

CORFs:

- CMS 1539 - Certification & Transmittal;
- CMS 855A - Enrollment Application;
- Legal Documentation of CHOW;
- CMS 359 - CORF Report for Certification to Participate in the Medicare Program;
- CMS 1561 - Benefits Agreement; and confirmation of eOCR Submission.
- Pre and Post Org Chart;
- Bill of Sale/ Stock Purchase Agreement, or Assignment and Assumption Agreement.

FQHCs:

- CMS 855A - Enrollment Application;
- Legal Documentation of CHOW;
- HRSA Grant Information (HRSA Grant must illustrate the name of the new grantor/new Buyer).

NOTE: For FQHCs, CHOWs will be directly handled by CPI/PEOG and MACs. Note, the package will not include a 1539 as there is no SA involvement. If the FQHC did not reject assignment, the new Buyer must ensure that any relevant grant information through HRSA is approved.

HHA:

- CMS 1539 - Certification & Transmittal;
- CMS 855A - Enrollment Application;
- Legal Documentation of CHOW;
- CMS 1572 - Home Health Agency Survey & Deficiencies Report;
- CMS 1561 - Benefits Agreement and confirmation of eOCR Submission.
- The CHOW package must also identify if the HHA provides any of the following services: Skilled Nursing; Physical Therapy; Speech Therapy; Occupational Therapy; Medical Social Services and Home Health Aide Services (see CMS Form 1572);
- Pre and Post Org Chart;
- Bill of Sale/ Stock.

The Medicare regulation at 42 CFR 424.550 limits automatic assignment of the provider agreement of a HHA which is sold, or changes majority ownership, within 36 months after the effective date of the HHA's initial enrollment in Medicare, or its most recent changes to majority ownership.

NOTE: If a CHOW is submitted, which includes subdivisions, in addition to the parent HHA, the CHOW will be processed to include all subdivisions and branches (including assignment of CCNs). In rare circumstances, a CHOW of an HHA may have branches, which both the Seller and the Buyer agree would not be part of the CHOW. In this case, the branches would need to either voluntarily terminate or apply as free-standing HHAs (initial enrollment).

For HHAs, their additional locations fall under the parent's Medicare provider agreement and CCN. The provider agreement of the entire HHA, including its branches, terminates **if a new owner rejected automatic assignment** of the existing Medicare HHA agreement.

NOTES FOR HHA: If a hospital-based HHA undergoes a CHOW and becomes freestanding, the HHA will be assigned solely to the geographic HH&H MAC. This will be a change from a provider-based HHA being assigned two MACs- the geographic HH&H MAC for reimbursement and the hospital's MAC for Audit.

If a freestanding HHA becomes hospital-based through a CHOW, the existing Reimbursement HH&H MAC remains for reimbursement purposes, and the hospitals' MAC becomes the Audit MAC.

In both cases, if the CMS 855A was approved by the "old" MAC, the enrollment case should be transferred to the appropriate MAC.

OPT/OSP:

- CMS 1539 - Certification & Transmittal;
- CMS 855A - Enrollment Application; Legal Documentation of CHOW;
- CMS 1856 - Request for Certification in the Medicare and/or Medicaid Program to Provide Outpatient Physical Therapy and/or Speech Pathology Services;

- CMS 1561 - Benefits Agreement and confirmation of eOCR Submission.
- Pre and Post Org Chart;
- Bill of Sale/ Stock.

PXR:

- CMS 1539 - Certification & Transmittal;
- CMS 855B - Enrollment Application;
- Legal Documentation of CHOW;
- CMS 1880 - Request for Certification as a Supplier of PXR Services under the Medicare Program

REMINDER/NOTES: A new owner (the buyer) may propose to relocate the organization concurrent with the CHOW. This would be considered as an address change of the existing provider and the new location may be surveyed to ensure that it meets all the applicable CoPs. (See Part II of the main SOP for additional information)

- However, if the relocation is to a site that is located in a different geographic area serving different patients than previously served and employing different personnel to serve those patients, then the new owner must be treated as a new provider in the Medicare program. (**Note**: If this occurs, the SOP here would not apply and this would be processed as a voluntary termination of the old owner's provider agreement and an initial application/enrollment for the new owner).
- For OPTs, their additional locations fall under the parent's Medicare provider agreement and CCN. The provider agreement of the entire OPT, including its extension locations, terminates **if a new owner rejected automatic assignment** of the existing Medicare agreement.

Part II –Administrative Changes

Many enrollment certification actions are not CHOWs, as outlined in the general SOP. These situations are generally when a provider/supplier changes names not due to a CHOW, or there is an administrative update to the provider agreement.

Administrative Changes

The below list highlights the most commonly seen administrative changes for these provider/supplier types and supplementary documentation or processes in addition to the guidance within the main SOP.

ASCs:

- **Relocation:** An existing Medicare-certified ASC that has relocated must submit a CMS-855B updating the location information to the appropriate MAC following the general SOP Part II. When an ASC moves to a new location, whether or not a survey of the new location should be conducted is at the SA's/AO's discretion once the recommendation for approval is received from the MAC.
    - In addition to following the main process (determination if the ASC continues to serve the same community served by the ASC at its original location) as outlined in the SOP, the SA/AO (if applicable) should also consider the following factors

on whether or not the ASC needs a survey upon relocation: 1) Past compliance history; and 2) Whether or not complex surgical procedures are being added that require new levels of sterility or infrastructure (for example: an ASC that previously provided only endoscopy services now adds orthopedic surgery for adults and pediatrics).

- **Multiple Locations**: If an entity owns multiple surgical locations and wishes them to participate in Medicare as an ASC, each location should seek separate certification and demonstrate independent compliance with the ASC CfCs as the regulations do not permit multiple ASCs to be certified under a single Medicare agreement. ASCs only have one surgical location per CMS Certification Number (CCN). ASCs are not permitted to share space, even when temporarily separated, with a hospital or Critical Access Hospital outpatient surgery department, or with a Medicare-participating Independent Diagnostic Testing Facility (IDTF). Certain radiology services that are reasonable and necessary and integral to covered surgical procedures may be provided.
  Also, provider-based determinations under 42 CFR §413.65 are not made for ASCs.

- **Cessation of Business:** It is not uncommon for small, single-specialty ASCs to be open one day a week or even a few days per month, for example. This becomes a challenge for SAs and AOs when attempting unannounced surveys. If the SA/AO is unable to conduct an unannounced survey after multiple attempts, the SA/AO should send a form CMS-1539 to the MAC if the evidence establishes a cessation of business (voluntary termination of the Medicare CCN) in accordance with 42 CFR 416.35(a)(3).

- **Temporary Closure**: If the ASC undergoes a temporary closure, due to repairs, remodeling, or the single surgeon owner being out for a period of time; it must notify the SA in writing. A temporarily closed facility may not retain its Medicare participation indefinitely. At the time of the temporary closure, the facility provides a projected date for resumption. The process will follow the guidance outlined in the main SOP. **Temporary closures must be approved by the SA or CMS Location. AOs are not able to approve temporary closures.**

CMHCs:

- **Change in Provider Location:** When the SA or CMS Locations is notified that a provider/supplier is moving, or has moved, its location, the SA will review the information to determine whether the provider/supplier is serving the same designated service area. If that is the case, the provider/supplier may maintain its current CMS Certification Number (CCN) and provider agreement. If a provider/supplier that is not operated by the State relocates to a different designated service area than the one originally approved by the CMS, the provider/supplier will be considered a new provider, its certification will be voluntarily terminated (Voluntary Termination SOP) and the provider must reapply for initial certification.

CORFs:

- **Shared/Leased Space**: A CORF may be established on the premises of another health entity even though the other entity is currently approved under Medicare as a provider or supplier of services. A CORF may not share a common space with the other entity unless

the CORF is able to fully function without interruption during its scheduled hours of operation.

- **Conversion**: An OPT/OSP (see below) primary location may convert to a CORF if it meets the CORF CoPs. Normally, the OPT/OSP provider will relinquish its OPT/OSP site (voluntary termination) unless it shares space with the CORF. To share space, an identifiable part of the OPT/OSP at the site must be set aside exclusively for the operation of the CORF and treatment of CORF patients during CORF hours of operation. In these situations, the OPT/OSP CCN and provider agreement would be voluntarily terminated after successful conversion.

FQHCs: For FQHCs requesting any administrative change (based on the general SOP), the FQHC will submit the CMS 855 to the MAC and include any supporting documentation for the request. CPI/PEOG will review and either approve or deny the request based on information received, including documentation from the FQHC (No SA involvement). We note, HRSA grant information may require updates based on the change request. FQHCs are expected to work with HRSA to ensure that information has been coordinated through HRSA. CPI/PEOG should verify that the HRSA Grant (eligibility requirement) reflects the change as well (e.g. name change; address changes; relocation- updated grant information).

HHA:

- **Address Changes:** When an existing HHA intends to move from its surveyed, certified location to a new site or location, it notifies the SA in writing of the proposed change of location, in accordance with Part II of the general SOP. The provider submits all required documentation including an amended Form CMS-855A before to the MAC.. The provider obtains CMS' approval of the new address before it provides Medicare services from the new address.
    - Upon receipt of a provider's notice and request for approval of the move to the new site or location, the SA will carefully evaluate the information, together with any supporting documentation from the provider and any other relevant information known to the SA in making its decision.
    - If a decision can be made on the written application and supporting documentation, CMS will grant or deny an approval without requiring a survey and will notify the MAC in accordance with the SOP.
- **Providing Services Across State Lines:** When a HHA provides services across State lines, each respective SA must be aware of and approve the action. Each SA must verify that applicable state licensure, personnel licensure, and other State requirements are met in its respective State. The provision of services across State lines is appropriate in most circumstances. Areas in which community services, such as hospitals, public transportation, and personnel services are shared on both sides of State boundaries are most likely to generate an extension of HHA services.
    - When a HHA provides services across State lines, it must be certified by the State in which its CCN is based, and its personnel must be qualified in all States in which they provide services.
    - The appropriate SA completes the certification activities. The involved States must have a written reciprocal agreement permitting the HHA to provide services in this manner.

    - For deemed facilities, based on licensure, the AO may need to verify/coordinate with the appropriate SA to ensure licensure requirements are met prior to sending the recommendation for approval to the MAC.
- **Cessation of Business**: There are instances in which surveyors may arrive at an organization to conduct a re-certification survey and find that there are no patients or the organization is no longer at the location on the CMS 855. (Refer to the Cessation of Business in the general SOP).

In general, HHAs would not require a survey for any administrative changes if it remains the same geographic location. The SA or AO (if applicable) will make the determination on survey needs based on the request received.

Outpatient Physical Therapy/Outpatient Speech Pathology (OPT/OSP): In OPTs, generally the most common changes include adding an additional practice location or extension location. For these administrative changes, please refer to the general SOP Part II as there is no deviation for processing.

Additional Considerations:

- **Leased Space:** Any space leased, rented, or dedicated for the provision of OPT services, including space within an Assisted Living Facility (ALF) or Independent Living Facility (ILF) that is designated for therapy service, must become a separately certified OPT or become approved as an extension location of a currently certified OPT. Leased or rented space that is dedicated to therapy services must be closed to non-therapy participants when services are being provided. For separately certified OPTs, the process will require the organization to submit for initial approval/enrollment. For adding an extension location, the process will follow the main SOP, which requires updates to the CMS 855.
    - There is no prohibition against an organization operating on the premises of a supplier (e.g., physician or chiropractor) or another provider as long as they are not operating in the same space at the same time.
- **Extension Locations:** While not different from the definition/process found under the main SOP, for OPTs extension locations are defined in 42 CFR 485.703.The mandatory services to be provided at the primary site are physical therapy or speech-language pathology services. Occupational therapy is an optional service. The extension location must also provide physical therapy and/or speech-language pathology services. The SA or AO will make the determination of whether or not to approve an extension location, per the steps outlined in the general SOP. In addition to OPT specific survey guidance, determination for approval should also include:
    - For a rehabilitation agency to establish an extension location across State lines, the affected SA must have a signed reciprocal agreement allowing approval of the extension location. For deemed OPTs, the AO will survey the location as needed, however there is no requirement for a reciprocal agreement as AOs are national in scope.
    - The SA should request the agency to submit the Form CMS-381, in addition to the modified CMS-855A whenever the agency requests to add a new practice location.
- **Off-Premise Activity**: OPTs are able to provide specific permissible off-premises activities at other locations. An example of an off-premises activity may also include a

community pool utilized in the provision of aquatic therapy not on the premises of the OPT. OPTs may only provide services at off-premises locations, such as Assisted Living Facilities (ALFs), Independent Living Facilities (ILFs), Long-term care facilities (LTCs), patient's private residence, on an intermittent basis when there is no ongoing or permanent presence of the OPT. There is no required CMS 855, unless determined this is an extension location and not off-premises activity.

Portable X-Ray (PXR):

- **Operating Across State Lines:** 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 State and local laws of each state in which they operate. The certifying SA in such instances 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.

In the event the provider decides to voluntarily terminate, the SA, CPI/PEOG and the MACs will follow the procedures outlined in the Voluntary Termination SOP.

CMS Certification Numbers (CCNs) & Effective Dates

Per the main SOP, CCNs will generally remain the same for all administrative changes. However, please note the following instructions below for provider differences.

ASC, CMHC, CORF, PXR: No deviation or additional documentation to highlight from the main SOP.

HHAs (Branch Locations): CMS PEOG assigns an identification number to every Medicare approved branch location linking the parent to the branch using a unique identifier. Each branch is numbered with the same assigned CCN as the parent with two modifications.

- **CCN Identifier:** There is a "Q" between the state code and four-digit provider designation plus three more digits for a 10-character branch identifier. Branch identification numbers are to be used only once. In the event that an HHA branch closes, its unique branch identification number is terminated and not re-used to identify another branch of that parent HHA. EXAMPLE:
    - ABC Home Health Agency in Alabama has three branches.
    - ABC Home Health Agency in Alabama = CCN number 017001.
    - ABC's branches would be assigned the branch identification numbers 01Q7001001, 01Q7001002, and 01Q7001003.

OPT/OSP (Extension Locations): The effective date of coverage for services provided from the extension location is the date the SA determines that the extension location meets all Federal requirements. This date will be included in the CMS notice letter. The organization should not begin providing services at the newly added practice location until it receives CMS's notice of its decision to approve or deny the new location.

- **CCN Identifier**: OPT extensions are identified by the assignment of a 10-digit alpha-numeric number. Each extension is numbered with the same CCN as the parent with two

modifications: (1) The letter "P" will be in the third position between the state code and the 4-digit provider designation; and (2) three additional digits are added to the end of the number. The last 3 digits are a one-up sequence number for each extension number starting with 001. These digits allow the capability of assigning up to 999 extensions to one OPT. The extension CCN will be used only once. In the event that an OPT extension closes, its unique extension identification number is terminated and will not be reused to identify another extension of that OPT.

- Example: Vibrant Physical Therapy has three extensions. Its CCN is 556599. Vibrant's three extensions would be assigned the numbers 55P6599001, 55P6599002, and 55P6599003.

Part III –Initial Certification and Enrollment

The SA will review all documents listed above (refer to CHOW section) from the provider/supplier as they are also required for an Initial Certification Application. The below provides an overview of addition requirements for these providers/suppliers which are supplementary to the main SOP. In general, the SA Documentation will include:

- CMS-1561-Health Benefit Agreement
- Office of Civil Rights- (Confirmation of OCR submission)
- CMS-1539 Certification & Transmittal (completed by SA)
- CMS 855A - Enrollment Application

ASCs: Participation as an ASC is limited to any distinct entity that operates exclusively for the purpose of providing surgical services to patients' not requiring hospitalization (i.e., an inpatient stay in a hospital) and in which the expected duration of services would not exceed 24 hours following an admission. The definition of an ASC at 42 CFR 416.2, does not allow the certified-ASC to have multiple locations or mix functions and operations with another entity in a common space during concurrent or overlapping hours of operations.

- Initial Enrollment documentation which the SA receives include Form CMS-377, (Exhibit 64) with a Certification and Transmittal, Form CMS-1539; Copies of the ASC Health Insurance Benefits Agreement, Form CMS-370 (Exhibit 65) are signed and processed in the same manner as provider agreements.

CMHCs: A CMHC is required to submit a certification statement, provided by an independent licensed professional, to certify that the CMHC client population meets the 40 percent requirement as specified in 42 CFR §485.918(b)(1)(v)(A) and 42 CFR §485.918(b)(1)(v)(B). The certification statement is required upon initial application to enroll in the Medicare program and as part of provider enrollment revalidation. The statements are submitted to the applicable MAC. Medicare enrollment may be denied or revoked in instances where the CMHC fails to provide the certification statement as required.

- The SA, CPI/PEOG and MAC, will follow the process outlined under Part III, Section III of the general SOP. Under Step #2, as part of the MAC review of the CMHC initial application, the MAC also reviews the facility certification statement that at least 40 percent of the CMHC's items and services are provided to non- eligible individuals it will forward an approval recommendation notice to the appropriate and the SA.

- The SA will schedule an initial survey for the CMHC according to the CMS Mission and Priority Document (MPD).

CORF: There are no specific documentation differences for CORFs outside of what is listed above in general.

FQHC's: Initial enrollment has transitioned as of March 2021. For specific initial enrollment, please refer to FQHC SOP for additional details.

Home Health Agencies (HHA): In addition to an onsite survey to determine compliance with the health and safety conditions of participation (CoP), an HHA applicant must now meet capitalization requirements, and complete the enrollment information contained on the Form CMS-855A, which includes the HHA's ownership information. CMS requires each HHA applicant to have provided skilled home health services to a minimum of 10 patients before a survey is conducted. At least 7 of the 10 required patients should be receiving care from the HHA at the time of the initial Medicare survey.

The HHA must have staff hired directly or through contract that provide all the services they are requesting. For example, CMS cannot approve OPT services if there are not OT staff working at the HHA.

The SA will make this determination during its review of the application received by the applicant.

OPT/OSP: There are no specific documentation differences for OPT/OSPs outside of what is listed above in general.

Portable X-Ray (PXR): In order to facilitate the process of determining whether portable x-ray equipment meets FDA standards, the SA must request the supplier to submit the following information on all unlabeled equipment prior to the survey or resurvey:

- Name of manufacturer;
- Equipment model number;
- Equipment serial number; and
- Date of manufacture (if available).

The SA checks the information with the State radiation health specialists who perform the equipment surveys. If doubt exists as to whether the equipment used by a particular x-ray supplier meets Federal standards, the SA forwards the case to the CMS Location for HSQB verification with the FDA. The SA must not certify or recertify the supplier of portable x-ray services until questions concerning the equipment's legality are resolved.

Part IV –Important Reminders & Resources

Important Reminders Resources

- In the case of an acquisition of a supplier by the direct owner of a hospital, and the combination of the supplier with a hospital (for example, the direct owners of a hospital acquire an ASC and combine it with the hospital as a hospital outpatient department under the hospital's Medicare provider agreement) CMS, when applicable uses, as applicable the hospital CCN.

Additional Resources

- CHOW, Administrative Changes; Relocations & Initials- General SOP
- SOM Chapter 2
- SOM Chapter 7
- SOM Appendix L (ASC Surveyor Guidance)
- SOM Appendix F (CMHC Surveyor Guidance)
- SOM Appendix K (CORF Surveyor Guidance)
- SOM Appendix B (Home Health Surveyor Guidance)
- SOM Appendix E (OPT Surveyor Guidance)
- SOM Appendix D (PXR Surveyor Guidance)

Attachment 4:
ESRD Facilities ADDENDUM
Transition Occurring on November 7, 2022

Purpose: The intent behind this Standard Operating Procedure (SOP) is to provide direction to the Survey Operations Group (SOG) locations, State Survey Agencies (SAs), the Center for Program Integrity (CPI)/Provider Enrollment Oversight Group (PEOG) and the Medicare Administrative Contractors (MAC) as it relates to the processing of certification activities.

Scope: The SOP covers multiple parts, including 1) changes of ownership (CHOWs); 2) Administrative Changes; and 3) Initial Certification and Enrollment. The SAs, CPI/PEOG, and the MACs will follow the general guidance provided in the SOP; however, **this Addendum also covers provider/supplier differences, nuances, and areas specific to End-Stage Renal Disease (ESRD) Facilities. This Addendum does not include Special Purpose Renal Dialysis Facilities, as these are used in limited circumstances, e.g., emergencies/disaster events.**

Notification to ESRD Networks: The SA and AO is responsible for notifying the ESRD Network for all changes to include **voluntary terminations, CHOWs, administrative changes and initial certifications**. The contact list for ESRD Networks can be found here: https://esrdnetworks.org/membership/esrd-networks-contact-information/.

General Information & Background

Definitions:

- **End-Stage Renal Disease (ESRD) Facilities:** ESRD is that stage of renal impairment that appears irreversible and permanent and requires a regular course of dialysis or kidney transplant to maintain life. Section 1802 of the Act provides that any individual entitled to Medicare may obtain health services from any institution, agency, or person qualified to participate in Medicare if that institution, agency, or person undertakes to provide that individual such services. Section 1881(b)(1) of the Act requires renal dialysis facilities to comply with the Conditions for Coverage (CfCs) for End-Stage Renal Disease (ESRD) Facilities which are in 42 CFR Part 494.

Participation & Survey/Certification Requirements:

- **Hospital-Based ESRD Facility:** A hospital-based ESRD facility is a separately certified ESRD facility that is an outpatient department of a hospital and meets the ESRD CfCs at 42 CFR Part 494. A hospital-based ESRD facility is owned and administered by a hospital and is physically located on the hospital campus. CMS determines whether a facility is a hospital-based ESRD facility under §413.174(c).

- **Satellite Renal Dialysis Facility (Hospital-Based):** A satellite renal dialysis facility is a hospital-owned and hospital-administered ESRD facility but is not located on the hospital's campus. A single hospital may have several satellite renal dialysis facilities. Each satellite facility is separately certified and surveyed; must independently meet the ESRD CfCs from other facilities owned by that hospital; and is assigned its own CCN.

- **Independent Renal Dialysis Facility:** An independent renal dialysis facility is any outpatient dialysis facility that does not meet the definition of a hospital-based dialysis facility at § 413.174(c) or a satellite renal dialysis facility. An independent renal dialysis facility may be physically located on the hospital campus, but is not owned, administered, or governed by the hospital. Independent renal dialysis facilities are separately certified and assigned their own CCN.

- **Special Purpose Renal Dialysis Facility (SPRDF) (§494.120):** This type of renal disease facility is temporarily certified to furnish dialysis at special locations on a short-term basis (i.e., up to 8 months in any 12 months) to a group of dialysis patients who would otherwise be unable to obtain treatment in the geographical area. We have defined **SPRDF for reference only; however, this work will remain with the CMS Locations as these are time-limited and only operate under limited circumstances, e.g., emergency/disaster situations.**

For home dialysis in a nursing home, there is no change in the existing processes or involvement by the MAC/CPI.

PART I- Changes of Ownership (CHOWs)

Providers or suppliers to which CHOW rules apply include ESRD facilities at 42 CFR 489.2. ESRD facilities will follow the CHOW process outlined in Part I of the general SOP and the processing instructions depending on the new owner/buyer accepting or rejecting automatic assignment.

The information below highlights required forms specific to ESRD facilities as part of a CHOW Package. The MAC may obtain only part of these documents during the initial request; however, the SA may need to follow up with the provider to obtain the remaining documentation. The final CHOW package supporting documentation should include the documents listed below:

ESRD Facilities:
- CMS-1539 - Certification & Transmittal;
- CMS-855A - Enrollment Application;
- Legal Documentation of CHOW;
- CMS-3427 - ESRD Application/Notification and Survey & Certification Report;
- The MAC will also need to verify the number of In-Center Hemodialysis Stations and modalities (In-Center Hemodialysis; In-Center Peritoneal Dialysis; Training and Support for Home Hemodialysis; Training and Support for Home Peritoneal Dialysis (CAPD/CCPD)).

Part II –Administrative Changes

Many enrollment certification actions are not CHOWs, as outlined in the general SOP. These situations are generally when a provider/supplier changes names, not due to a CHOW or an administrative update to the provider agreement.

Administrative Changes- ESRD Facilities:
In accordance with the general SOP, the SA or AO will be responsible for confirming the type of administrative request and providing the recommendation for approval to the MAC once a survey has or has not been conducted based on the criteria outlined. **We further note, unlike certain other providers/suppliers, ESRD facilities that seek to expand by adding additional locations or sites**

that are not located in the main premises of the certified facility would generally require a new CCN and separate certification.

In general, for ESRD facilities, additional services or stations added (e.g. ESRD home dialysis in NHs, additional modalities) are the most frequently requested changes, which may require the SA or AO to survey and be responsible for determining the changes requested by the ESRD. **The ESRD facility is required to submit the CMS-3427 form to the SA and AO (as applicable). The SA will update the national database for all administrative changes and the AO (if applicable) will remain responsible for updating the ASSURE database. For any ESRD facility relocations, the CMS-855 must also be submitted to the MAC.**

Relocations (Provider-based to free-standing or vice versa):

- **Hospital-Based ESRD Relocations:** If a hospital-based ESRD facility relocates to an off-campus location, its CCN will be retired, and the facility will be assigned a new CCN. Note, as part of the ESRD relocation request; the facility must also submit a revised Form CMS-3427 to the SA or AO (as applicable).
    - If the hospital-based ESRD facility is located off-site but functions under a common hospital governing body, operates under the hospital's policies and practices, continues to serve the same community, and utilizes the same staff at this new location, then the CCN will correspond to renal satellite facilities.
    - If the hospital-based ESRD facility relocates to a site located off the hospital campus and is no longer operationally, administratively, or financially integrated with the hospital, the CCN will be assigned a new CCN that corresponds to an independent dialysis facility (refer to the general SOP and Initial Certification processes for further guidance).
- **For other relocations:** Generally, a relocation survey is not required when an ESRD facility (1) relocates to a new physical location but is still serving the same patients and employing the same staff, (2) changes its location on campus, or (3) changes its location within the original address. The SA or AO determines the need to perform an onsite survey upon request of the relocation by the ESRD facility. Before relocating any patients, the ESRD facility must submit evidence to the SA or AO that water testing at the new location was performed, and the results were determined to be within acceptable ranges. The ESRD facility must also submit a revised floor plan to the SA or AO to confirm adequate space for stations and attest to compliance with the Life Safety Code requirements.
    - If a dialysis facility permanently relocates, it must remain the same at its new location. The SA or AO determines that the facility serves the same patients with the same staff.
    - The SA or AO will also request that the ESRD facility provide a notification letter indicating they are ready for a survey after the first patient.
- **Out of State- Relocation**: If an ESRD facility relocates to another state, it is considered a voluntary termination, and the facility's Medicare CCN is terminated. The relocated facility must seek Medicare participation as an initial applicant in the new State. The relocated facility would be certified as a new ESRD facility and have a new CCN once it demonstrates compliance with all federal requirements.
    - NOTE: There are instances when a certified ESRD facility will provide home hemodialysis or home peritoneal dialysis services to patients or nursing home residents who reside within close proximity of state lines (which in some cases may be across the street). No special approval or agreement is required for a dialysis facility to provide home training and support services to patients in a bordering state.

Adding In-Center Dialysis Stations; Expansion of Modalities:
These are the only administrative changes that do not require a CMS-855 **to be sent to the MAC**. **The SA will be responsible for updating the national database system (including information on deemed ESRD facilities from the AO).**

However, SAs and AOs should follow the below guidance:

- **Adding In-Center Dialysis Stations:** When a dialysis facility wishes to increase the number of its approved in-center dialysis stations, it must submit a new Form CMS-3427 ESRD Application and Survey and Certification Report to the applicable SA or AO (if deemed). The dialysis facility must specify the number of additional stations requested and include evidence that adequate space is available for the stations in consideration of safety and infection control and include a summary explanation of any building renovations that will be necessary for the addition of stations. **The ESRD facility will be required to submit the CMS 3427 form to the SA and AO (as applicable), who will review, approve/deny. The AO should notify the SA of the facility's approval/denial. The SA will be responsible for updating the CMS 3427 in the national database system with the new number of stations.**

  The SA or AO (as applicable) will request and review a facility floor plan, with the proposed additional stations shown, as part of determining whether to approve or deny the request. **If the review confirms adequate space for the addition of stations, no onsite review is required**.

- **Adding Additional Services:** An ESRD facility may choose to add additional services to their existing approved services. Additional services are added when a provider/supplier requests to add services, such as home dialysis services for an ESRD facility. For adding additional services, the MAC must be notified. An ESRD may add services as soon as they have a patient treated with or trained in that modality (e.g., in-center hemodialysis (HD), home HD, or home peritoneal dialysis). Other provider/supplier-types may not require a survey for additional services until the next survey cycle. As noted above, if an ESRD facility seeks to provide additional services within the same location (on-premise) and is seeking to add a suite, the ESRD CCN would remain the same. Off-site locations beyond the certified location would require the ESRD facility to apply as an initial applicant. Existing regulations require that dialysis services are provided directly on its main premises or on other premises that are contiguous with the main premises (42 CFR 494.180(d)).

- **Expansion of Modalities/Change in Stations**: When a dialysis facility wishes to increase the number of its approved in-center dialysis stations or change stations, it must submit a new Form CMS-3427 ESRD Application and Survey and Certification Report to the appropriate SA or AO (as applicable). The dialysis facility must specify the number of additional stations requested and include evidence that adequate space is available for the stations in consideration of safety and infection control and include a summary explanation of any building renovations that will be necessary for the addition of stations.

  The MACs need to update relevant information for billing purposes. Therefore, the SA and AO (as applicable) need to notify the MAC of a change in modalities and services via the CMS-1539 (comparable for AO) in accordance with the PIM, Chapter 10, Section 10.2.1.3 (End-Stage Renal Disease Facilities (ESRDs)).

  When a facility submits a request for the addition of a modality or service, it must submit a revised Form CMS-3427 to the SA or AO. A revised CMS-3427 is required when adding or eliminating the following dialysis modality/service(s):

- In-center hemodialysis
- In-center nocturnal hemodialysis
- In-center peritoneal dialysis
- Home hemodialysis training and support
- Home peritoneal dialysis training and support
- Dialysis in the Nursing Home setting
- Dialyzer reprocessing and reuse.

- The SA or AO (as applicable) will notify the MAC (consistent with the general SOP) of its recommendation of approval or denial of the addition via the CMS-1539 (or comparable form for the AOs).
- The SA or AO (if applicable) will also notify the ESRD Network. The contact information for the ESRD Network can be found here: https://esrdnetworks.org/membership/esrd-networks-contact-information/
- If the provider/supplier is not currently approved for a similar service (to the one being added), the SA or AO may complete an onsite survey. **Many additions of services can be completed via desk review.** The survey or desk review documentation should be included with the CMS-1539 (or comparable for AOs).

Temporary Closures: A temporary closure may occur as a planned event to allow repair or remodeling or as an unplanned event due to damage from a natural or man-made disaster. The facility must notify the SA in writing of any temporary closure of the facility that extends more than one day of operation. Once the facility has reopened, the SA will determine whether an onsite review is required based on the submitted documentation. For additional guidance, please refer to the general SOP (Part II, Section II).

If the provider/supplier decides to voluntarily terminate from the program, the SA, CPI/PEOG, and the MACs will follow the procedures outlined in the Voluntary Termination SOP.

CCN Guidance:
If the administrative change results in a CCN change, the MAC letter should also include a copy of the change notice to the ESRD Network for the specific ESRD facility.

The CCN of the ESRD facility may remain the same in the following situations:

- Generally, a change in modalities does not impact the ESRD CCN.

- A hospital-based ESRD facility retains ownership of its facility but contracts with another entity for management of the facility;

- The ESRD facility is purchased by another ESRD facility of the same type. For example, an independent facility by independent facility or hospital-based by hospital-based; and

- The geographic location of the ESRD facility is changed within the same state. If a geographic location is changed to another state, the ESRD facility at the old location must be terminated, and the relocated ESRD facility must apply as a new applicant and qualify for a new identification number in the state to which it moved.

- It is conceivable that a hospital-based ESRD facility could have a 2300-2499 number assigned to the location on the hospital's premises and one or more 3500-3699 numbers for those locations (satellites) off the premises (each satellite is given a separate 3500-3699 number). If an ESRD facility that is assigned a 2300-2499 number moves off the hospital's premises and is determined

to be a satellite, it should receive a number in the 3500-3699 series. However, if a satellite changes its address but is still considered off the hospital's premises, it should retain the 3500-3699 number it was originally issued rather than being issued a new 3500-3699 number.

Changes in CCNs may occur based on the below:

- If an ESRD facility relocates to another state, it is considered a voluntary termination (processed by the MACs), and results in the facility's Medicare CCN being terminated by CMS (PEOG). The relocated facility must seek Medicare participation as an initial applicant in the new State. The ESRD facility would be certified as a new ESRD facility and have a new CCN once it demonstrates compliance with all federal requirements.

- If a hospital-based ESRD facility relocates to an off-campus location but continues to serve the same community and utilizes the same staff at this new location, its CCN will be retired, and the facility will be assigned a new CCN. This is not a voluntary termination.

Part III –Initial Certification and Enrollment

For ESRD facilities, initial certifications and enrollments will follow Part III, Section III of the general SOP. However, the information below provides additional guidance and documentation requirements for ESRDs as part of initial certification.
NOTE:

- All initial certifications for ESRD facilities must receive an onsite survey.
- The process for SPRDFs are also not transitioning at this time. An SPRDF cannot convert to a permanent ESRD facility. These SPRDFs seeking to be ESRD facilities must reapply as a new applicant (new CMS Form 855 and CMS 3427) and receive an initial certification survey.

The prospective ESRD supplier completes the Form CMS-855A as part of the application package per the general SOP. Additionally, to be certified in the Medicare program as an ESRD facility, a facility must:

- Submit a CMS-855A Provider Enrollment Application
- Complete Part I of Form CMS-3427A, "End Stage Renal Disease Application and Survey and Certification Report;"
- Have provided care to a minimum of one patient per modality*; and
- Comply with all federal requirements, including the ESRD Conditions for Coverage

Where required by State law, a certificate of need (CON) must be submitted by the facility unless it is a SPRDF. The SA should confirm that a CON is submitted before performing an initial certification survey. NOTE: SPRDFs will follow existing guidance and will not be transitioned under this process.

The SA will review all documents above for a CHOW from the ESRD facility as these documents are also required for an Initial Certification Application.

The one patient per modality includes current patients on the census, so observation of care is possible. Compliance with the CfCs is done via an onsite survey of Health & LSC requirements.

The SA forwards its recommendation for certification or denial to the MAC. The MAC will forward the final determination to the facility. CMS (PEOG) assigns the ESRD facility a CMS Certification Number (CCN) if the facility is approved for certification. CMS (PEOG) completes the certification in the national survey data system.

*The one minimum patient per modality review process does not apply for approval of an in-center PD program if the facility is simultaneously requesting approval for home PD training and support AND there is a minimum of one patient on the census for that program. To determine compliance with the facility's home training program and care provisions, the patient for the home program must be a new patient for the facility under review, i.e., the transfer of an already trained patient would not be sufficient to determine compliance with the applicable requirements.

Initial Enrollment- CMS Certification Numbers (CCNs) & Effective Dates

For ESRD facilities, CCNs will be assigned by PEOG according to the information provided above for general CCN guidance. The effective date of participation in the Medicare program, i.e., of the provider agreement or supplier approval issued by the CMS, may not be earlier than the date on which the provider or supplier meets all Federal requirements (see 42 CFR 489.13).

Use the CCN ranges noted below for the facility types indicated:

Both reimbursement and survey purposes need to assign the ESRD facility the correct CCN.
ESRD facilities and their CCN are as follows:

2300-2499	Chronic Renal Disease Facilities (Hospital-Based)
2500-2899	Non-Hospital Renal Disease Treatment Centers (Independent)
2900-2999	Independent Special Purpose Renal Disease Facilities
3500-3699	Renal Disease Treatment Centers (Hospital Satellites)
3700-3799	Hospital-Based Special Purpose Renal Dialysis Facilities

Special purpose renal dialysis facilities are assigned CCNs in the 3700-3799 series when owned and administered by a hospital and in the 2900-2999 series for independent facilities.

Part IV –Important Reminders & Resources

Important Reminders Resources

- The SA date-stamps all Form CMS-3427s ("End Stage Renal Disease Application and Survey and Certification Report") and application-related correspondence received and review the forms and documentation for accuracy and completeness.

Additional Resources

- CHOW, Administrative Changes; Relocations & Initials- General SOP
- SOM Chapter 2
- SOM Chapter 7

Attachment 5:
Hospice ADDENDUM
Transition Occurring on November 7, 2022

Purpose: The intent behind this Standard Operating Procedure (SOP) is to provide direction to the Survey Operations Group (SOG) (later referred to as CMS Locations), State Survey Agencies (SAs), Accrediting Organizations (AOs), and the Center for Program Integrity (CPI)/Provider Enrollment Oversight Group (PEOG) and the Medicare Administrative Contractors (MAC) as it relates to the processing of changes of ownership (CHOWs), administrative changes (name, address, branch locations, additional services, relocations, etc.), and initial surveys and enrollment.

Scope: The SOP covers multiple parts to include 1) CHOWs; 2) Administrative Changes; 3) Initial Certification and Enrollment. The SAs, CPI/PEOG, and the MACs will follow the general guidance provided in the SOP, however **this Addendum also covers provider differences, nuances, and areas specific to Hospice.**

General Information & Background

Definitions:

In Medicare, the general distinction between providers and suppliers is that providers are parties who care for patients awaiting, receiving, or recuperating from treatment by intervening practitioners. In Medicare, the term suppliers" includes those who furnish goods and services used in care and treatment.

- **Hospice:** A hospice is a public agency or private organization or a subdivision of either of these that is primarily engaged in providing care and services to terminally ill individuals, meets the CoPs for hospices, and has a valid Medicare provider agreement. Section 1861(dd) of the Act defines hospice care and the hospice program and 42 CFR part 418 sets forth the Medicare hospice conditions of participation. Further, 42 CFR 418.3 defines "terminally ill individuals" as individuals having a "medical prognosis that the individual's life expectancy is 6 months or less."

Participation & Survey/Certification Requirements:

- **Hospice:** Although some hospices are located as part of a hospital, skilled nursing facility (SNF), and home health agency (HHA), hospices must meet specific CoPs and be separately certified and approved for Medicare participation as a hospice provider of services. (See Exhibit 129 for "Hospice Survey and Deficiencies Report," Form CMS-643, and Exhibit 72 for "Hospice Request for Certification in the Medicare Program," Form CMS-417.)

PART I- Changes of Ownership (CHOWs)

Hospice will follow the CHOW process outlined in Part I of the general SOP and as applicable, the processing instructions depending on the new owner/buyer accepting or rejecting automatic assignment. The below highlights forms which are required specific Hospice suppliers as part of a CHOW Package. Accrediting Organizations (AOs) will be copied on all Hospice CHOWs.

The MAC may obtain only part of these documents during the initial request, however the SA may need to follow up with the provider to obtain the remaining documentation. The final CHOW package supporting documentation should include the documents listed below:

- **Hospice:**
  - CMS 1539 - Certification & Transmittal;
  - CMS 855A - Enrollment Application;
  - Legal Documentation of CHOW; CMS 417 - Hospice Request for Certification in the Medicare Program;
  - CMS 643 - Hospice Survey & Deficiencies Report;
  - CMS 1561 - Benefits Agreement and confirmation of eOCR Submission.
  - Pre and Post Org Chart;
  - Bill of Sale/ Stock Purchase Agreement, or Assignment and Assumption Agreement.

  NOTE: For Hospices, their additional locations fall under the parent's Medicare provider agreement and CCN. The provider agreement of the entire hospice, including its multiple locations, terminates **if a new owner rejected automatic assignment** of the existing Medicare agreement.

  NOTES FOR HOSPICE: If a hospital-based Hospice undergoes a CHOW and becomes freestanding, the Hospice will be assigned solely to the geographic HH&H MAC. This will be a change from a provider-based Hospice being assigned two MACs- the geographic HH&H MAC for reimbursement and the hospital's MAC for Audit.

  If a freestanding Hospice becomes hospital-based through a CHOW, the existing Reimbursement HH&H MAC remains for reimbursement purposes, and the hospitals' MAC becomes the Audit MAC.

  In both cases, if the CMS 855A was approved by the "old" MAC, the enrollment case should be transferred to the appropriate MAC.

  NOTES:

  - A new owner (the buyer) may propose to relocate the organization concurrent with the CHOW. This would be considered as an address change of the existing provider and the new location may be surveyed to ensure that it meets all the applicable CoPs. (See Part II of the main SOP for additional information)
  - However, if the relocation is to a site that is located in a different geographic area serving different patients than previously served and employing different personnel to serve those patients, then the new owner must be treated as a new provider in the Medicare program. (**Note**: If this occurs, the SOP here would not apply and this would be processed as a voluntary termination of the old owner's provider agreement and an initial application/enrollment for the new owner).

Part II –Administrative Changes

Many enrollment certification actions are not CHOWs. These situations are generally when a provider/supplier changes names not due to a CHOW, or there is an administrative update to the provider agreement.

Administrative Changes –Hospice:
The below list highlights the most commonly seen administrative changes for these provider/supplier types and supplementary documentation or processes in addition to the guidance within the main SOP.

HHA and Hospice:

- **Address Changes:** When an existing HHA or hospice intends to move from its surveyed, certified location to a new site or location, it notifies the SA in writing of the proposed change of location, in accordance with Part II of the general SOP. The provider also notifies its MAC and submits all required documentation including an amended Form CMS-855A before CMS approval can be granted. The provider obtains CMS' approval of the new address before it provides Medicare services from the new address.
    - Upon receipt of a provider's notice and request for approval of the move to the new site or location, the SA will carefully evaluate the information, together with any supporting documentation from the provider and any other relevant information known to the SA in making its decision.
    - If a decision can be made on the written application and supporting documentation, CMS will grant or deny an approval without requiring a survey and will notify the MAC in accordance with the SOP.
- **Providing Services Across State Lines:** When a hospice provides services across State lines, each respective SA must be aware of and approve the action. Each SA must verify that applicable state licensure, personnel licensure, and other State requirements are met in its respective State. The provision of services across State lines is appropriate in most circumstances. Areas in which community services, such as hospitals, public transportation, and personnel services are shared on both sides of State boundaries are most likely to generate an extension of hospice services.
    - When a hospice provides services across State lines, it must be certified by the State in which its CCN is based, and its personnel must be qualified in all States in which they provide services.
    - The appropriate SA completes the certification activities. The involved States must have a written reciprocal agreement permitting the hospice to provide services in this manner.
    - For deemed facilities, based on licensure, the AO may need to verify/coordinate with the appropriate SA to ensure licensure requirements are met prior to sending the recommendation for approval to the MAC.
- **Cessation of Business**: There are instances in which surveyors may arrive at an organization to conduct a re-certification survey and find that there are no patients or the organization is no longer at the location on the CMS 855.

Hospice: In general, the only time a hospice would require a survey for any administrative changes would be if the hospice provides inpatient services. The SA or AO (if applicable) will make the determination on survey needs based on the request received.

CMS Certification Numbers (CCNs) & Effective Dates

Per the main SOP, CCNs will generally remain the same for all administrative changes. However, please note the following instructions below for provider differences.
Hospice (New Site/Location/Multiple Locations): A hospice may not bill for services provided from the new site or location and should not bill Medicare until the new site or location has been approved by CMS. The effective date of coverage for services provided from the new location is the date CMS grants approval to the hospice's request to change locations.

Part III –Initial Certification and Enrollment

The SA will review all documents listed above for a CHOW from the provider as they are also required for an Initial Certification Application. The below provides an overview of addition requirements for these providers/suppliers which are supplementary to the main SOP. The SA Documentation will include:

- CMS-1561-Health Benefit Agreement
- Office of Civil Rights- (Confirmation of OCR submission)
- CMS-1539 Certification & Transmittal (completed by SA)
- CMS 855A - Enrollment Application
- CMS 417-Hospice Request for Certification in the Medicare Program

Hospice: If a prospective provider moves after its location has been surveyed and/or accredited but prior to a certification determination by CMS, the prospective provider's application for certification becomes incomplete.

Initial Enrollment- CMS Certification Numbers (CCNs) & Effective Dates

Use the following CCN ranges for the facility types indicated:

- **Hospice:** 1500-1799 Hospices

Part IV –Important Reminders & Resources

Additional Resources

- CHOW, Administrative Changes; Relocations & Initials- General SOP
- SOM Chapter 2
- SOM Appendix M (Hospice Surveyor Guidance)

Attachment 6:
Hospitals (includes Transplant Programs & Psychiatric Hospitals)
ADDENDUM
Transition Occurring on November 7, 2022

Purpose: The intent behind this Standard Operating Procedure (SOP) is to provide direction to the Survey Operations Group (SOG) locations and State Survey Agencies (SAs). Accrediting Organizations (AOs) and the Center for Program Integrity (CPI)/Provider Enrollment Oversight Group (PEOG) and the Medicare Administrative Contractors (MAC) as it relates to the processing of certification activities. Corresponding Change Requests will be issued to MACs in accordance with existing directives and guidance requirements for MACs.

Scope: The SOP covers multiple parts, including 1) changes of ownership (CHOWs); 2) Administrative Changes; and 3) Initial Certification and Enrollment. The SAs, AOs, CPI/PEOG, and the MACs will follow the guidance provided in the SOP; however, **this Addendum covers provider differences, nuances, and areas specific to Hospitals (including Transplant & Psychiatric Hospitals).**

General Information & Background

Definitions:

- **Hospitals:** A hospital is defined in §1861(e)(1) of the Act. A hospital is an institution primarily engaged in providing inpatient diagnostic and therapeutic services or rehabilitation services by or under the supervision of physicians. The remainder of §1861(e) defines a hospital eligible for Medicare participation. 42 CFR part 482 sets forth the CoPs for hospitals, including psychiatric hospitals.

- **Psychiatric Hospitals:** Section 1861(f) of the Act defines Medicare eligible psychiatric hospitals. The term psychiatric hospital means an institution that is primarily engaged in providing, by or under the supervision of a Doctor of Medicine or Osteopathy, psychiatric services for the diagnosis and treatment of mentally ill persons; satisfies the requirements of §§1861(e)(3) through (e)(9) of the Act (general hospital requirements); maintains clinical and other records on all patients as the Secretary finds necessary to determine the degree and intensity of the treatment provided to individuals entitled to hospital insurance benefits under Part A; and meets such staffing requirements as the Secretary finds necessary for the institution to carry out an active program of treatment for individuals receiving services in the institution. The regulatory requirements (transplant CoPs) are found in 42 CFR 482.60 – 42 CFR 482.62.

- **Transplant Programs:** A transplant program is a component within a transplant hospital that provides transplantation of a particular type of organ, including; the heart, lung, liver, kidney, pancreas, or intestine. All organ transplant programs must be located in a hospital with a Medicare provider agreement. In addition to meeting the transplant CoPs, the transplant program must also comply with the hospital CoPs (specified in 42 CFR §482.1 through §482.57).

Participation & Survey/Certification Requirements:

- **Hospitals:** Hospitals must comply with federal requirements set forth in the Medicare CoPs at 42 CFR Part 482. A CMS-approved AO deems the majority (approximately 82%) of hospitals.

- **Psychiatric Hospitals:** Psychiatric Hospitals must meet the Medicare CoPs found in 42 CFR 482.60-482.62. Specifically, however, psychiatric hospitals must also meet all the Medicare CoPs for hospitals.

- **Transplant Programs:** Organ transplant programs must comply with the federal requirements set forth in the Medicare CoPs to be eligible to receive Medicare payments. In addition to meeting the CoPs for Transplant Programs in 42 CFR Part 482, Subpart E, transplant programs must also meet the Hospital CoPs specified in §§482.1 through 482.57.

NOTE: Only Hospitals and Psychiatric Hospitals have CMS-approved AOs (deemed). There are no CMS-approved AOs for Transplant Programs.

General Guidance- CMS Certification Numbers (CCNs) & Effective Dates
Use the following CCN ranges for the facility types indicated:

- **Hospitals:**
  - 0001-0879 Short-term (General and Specialty) Hospitals
  - 0880-0899 Reserved for hospitals participating in ORD demonstration project
  - 1200-1224 Alcohol/Drug Hospitals (Numbers Retired)
  - 2000-2299 Long-Term Care Hospitals (Excluded from IPPS)
  - 3000-3024 Formerly Tuberculosis Hospitals (Numbers Retired)
  - 3025-3099 Rehabilitation Hospitals (Excluded from IPPS)
  - 3300-3399 Children's Hospitals (Excluded from IPPS)

  EXCEPTION- Effective as of the cost reporting period beginning on or after October 1, 2019, an IPPS-excluded hospital is no longer precluded from having an IPPS-excluded psychiatric and/or rehabilitation unit. Note: An IPPS-excluded hospital may not have an IPPS-excluded unit of the same type (psychiatric or rehabilitation) as the hospital (for example, an Inpatient Rehabilitation Facility (IRF) may not have an IRF unit).

  Special Numbering System for Units of Hospitals That Are Excluded From the Inpatient Prospective Payment System (IPPS), CAHs, and both Hospitals and CAHs with Swing-Bed Approval
  An alpha character in the third position of a hospital's CCN identifies either its swing bed approval or its status as an IPPS-excluded rehabilitation or psychiatric unit. The first two (2) digits identify the State in which the provider is located. The third position (alpha) identifies the unit type or swing-bed designation. The last three (3) digits must be exactly the same as the last three (3) digits of the CCN of the hospital operating the unit(s).
  CMS assigns the following alpha characters in the third position as indicated:
  - S - Psychiatric Unit of a Short-Term, Cancer, Children's, LTCH, or Rehabilitation Hospital
  - T - Rehabilitation Unit of a Short-Term, Cancer, Children's, LTCH, or Psychiatric Hospital
  - U - Swing-Bed Approval for Short-Term Hospitals
  - W- Swing-Bed Approval for Long-Term Care Hospitals

Note: CMS SOG will remain responsible for the below-listed CCNs since CAHs remain with SOG for issuance (not transitioning to CPI/PEOG)

- M - Psychiatric Unit of a CAH
- R - Rehabilitation Unit of a CAH
- Z - Swing-Bed Approval for CAHs

- **Psychiatric Hospitals:** 4000-4499 Psychiatric Hospitals (Excluded from IPPS)

- **Transplant Programs:** 9800-9899 Transplant Centers. Transplant programs are the exception to the rule that providers only have one CCN. In the case of a hospital with a transplant program, the hospital will have a CCN, and the transplant program will have its own CCN.

PART I- Changes of Ownership (CHOWs)

Hospitals, Psychiatric Hospitals, and Transplant Programs will follow the CHOW process outlined in Part I of the general SOP. As applicable, the processing instructions depend on the new owner/buyer accepting or rejecting the automatic assignment. The below information highlights required forms specific to Hospitals, Psychiatric Hospitals, and Transplant Programs as part of a CHOW Package.

If, during the initial request and review by the MAC, the MAC determines documentation related to enrollment is missing, the MAC will follow existing PIM guidance. The SA may need to follow up with the provider to obtain the remaining documentation. The MAC may also communicate with the SA/AO on missing documentation if documentation is received after the initial recommendation is sent to the SA/AO.

However, supporting documentation for Hospitals, Psychiatric Hospitals, and Transplant Programs submitted to the MAC from the SA for completion of the final approval/denial must include CMS 855A - Enrollment Application; Legal Documentation of CHOW; CMS 1561 - Benefits Agreement; and Confirmation of eOCR Submission. The final CHOW package supporting documentation should include these documents. For hospitals and psychiatric hospitals, the CHOW package must also include the listed information below (as applicable).

- A statement or other documentation that specifies whether the hospital has Excluded Units (Rehabilitation Unit; Psychiatric Unit; Swing Beds). In general, the form CMS-437 is used for Psych Units and the form CMS-437A is used for Rehab Units. If the hospital has a transplant program, it must provide this information.

- The SA also includes EXHIBIT 286 HOSPITAL/CAH DATABASE WORKSHEET. The SA will update the national database system. Further, there may be instances in which there will be separate CHOW recommendations from the MAC for the unit(s) from a hospital. This process will continue to be processed without change.

Combination of Medicare-participating Hospitals:

In accordance with the provider-based rules at 42 CFR §413.65, a hospital may operate one or more of the following under one Medicare provider agreement and associated CCN: (1) one or more off-campus outpatient departments; and/or (2) one or more inpatient campuses (with one being the "main" campus and the other(s) called either "remote locations" or "satellites," depending on the type of hospital). Therefore, under the existing provider-based rules, it is possible for the owner(s) of an existing Medicare-participating hospital to acquire another Medicare-participating hospital, and make the acquired Hospital B a remote location or second campus of Hospital A.

If two or more Medicare-participating hospitals with the same owner wish to consolidate under one Medicare provider agreement and one CCN, that action will be considered an administrative type change versus a formal CHOW. The owner must submit a CMS-855 to the MAC reflecting the change of information (name change- refer to Administrative Changes Section II) and/or ownership of non-surviving hospital(s) in order to combination the facilities under a single CCN and provider agreement. This provision does not apply where there is a proposed consolidation with a provider owned by related organization (e.g. a parent, subsidiary corporation, limited partnership or other related entity), which is considered a CHOW. The acquiring provider must assume the provider agreement and all liabilities in order to bill under a combined CCN or undergo a new survey.

In these situations, SAs must follow existing guidance under QSO Memo 13-60 to determine if the request and actions to combine multiple Medicare-certified hospitals under a single provider agreement and CCN should be recommended for approval to the MAC. QSO Memo 13-60 prescribes the process by which the non-surviving hospital(s)'s CCNs are retired by the SA and MAC.

An IPPS-excluded unit or an excepted off-campus based hospital department cannot be a CHOW separately. A buyer must purchase and accept assignment of the previous owner's associated provider agreement in order to retain the special status associated with the units, and all other regulatory requirements for the units must also be met. *See* 42 C.F.R. § 412.29(c)(3); 42 C.F.R. § 419.48(b); 81 Fed. Reg. 79,709, 79,719 (Nov. 14, 2016). For all IPPS-excluded units and hospitals, the SA must consult with the CMS Location for any changes of ownership before any recommendation of approval/denial of a CHOW.

NOTE: In the event the existing provider agreement of the non-surviving hospital is rejected by the surviving hospital, the SA must recommend voluntary termination of the provider agreement in accordance with 42 CFR §489.52 and QSO Memo 13-60. The surviving hospital is ineligible for payment until their new location meets all requirements established in QSO Memo 13-60. The SAs must inform the MAC of the situation and the effects when referring the case via CMS 1539.

SA recommendations to the MAC via the CMS 1539 must clearly state the following when recommending combinations for approval:

- The Name, Location, and CCN of the surviving hospital will be the main information on the CMS 1539.
- The Name, main location, and CCN of the non-surviving hospital(s) must be included in Section 16 or Section 30 of the CMS 1539.
- Any IPPS-excluded units or status that are changing must be addressed and reported in Section 16 or 30 of the CMS 1539 to the MAC.
- If the action will result in voluntary termination in accordance with QSO Memo 13-60, that recommendation must be clear in Section 16 or 30 of the CMS 1539 and must indicate the voluntary termination was due to rejection of the existing provider agreement(s).

Provider-based Determinations Retained (Hospitals) - 42 CFR §413.65

- During a change of ownership, existing provider-based status is retained of the acquired, leased, or newly operated hospital unless the new owner/operator rejects the automatic assignment of the existing provider agreement of the acquired, leased, or newly operated hospital.

- Please note that during the combination of one or more hospitals, as described above and in QSO Memo 13-60, the locations of the non-surviving hospital must continue to meet the provider-based rules in order to eligible for combination. Concerns regarding status and eligibility of newly acquired, leased, or operated locations should be referred to the hospital's MAC, or the CMS Location's office of OPOLE-IFM for review.

- **Transplant Programs:** CHOWs do not occur in transplant programs because the change of ownership can only be at the hospital level, not at the transplant program level.

CHOWs Involving Acquisition/Mergers & Consolidations of Hospitals

When a new owner acquires a Medicare participating provider, this is a change of ownership in the corporate sense. A change of ownership must always be reported on the CMS-855 as a change of information. Many, but not all, changes of ownerships result in a Medicare CHOW (assignment of the Medicare provider agreement along with all conditions and liabilities to a new owner). Consult SOM Chapter 3210 and PIM Section 10.6 as applicable for additional discussion of Medicare CHOW situations.

In general, a change in the legal governing body that operates the provider organization is a Medicare CHOW. Thus, the acquisition or transfer of corporate stock in a hospital is not a CHOW. Refer to 42 C.F.R. 489.18(a)(3). This is because the governing body that has legal responsibility for operating the provider has not changed.

A transaction that results in the acquisition and merger of two or more Medicare-enrolled entities is a CHOW. For instance, suppose Hospital A and Hospital B participate in Medicare, each with its own CCN and provider agreement. The owner of Hospital A decides to acquire Hospital B and then merge the two hospitals under Hospital A's CCN. In this scenario, if the owner of Hospital A accepts assignment of Hospital B's provider agreement, there is a CHOW of Hospital B and Hospital B's CCN is retired. If the purchaser of Hospital B does not accept assignment of Hospital B's provider agreement, Hospital A is not eligible for Medicare payment for services at the new Hospital A-Campus 2 until it has completed a process analogous to that applied to an initial applicant for Medicare enrollment. This is the case even though Hospital A-Campus 2 will not be separately enrolled in Medicare.

A transaction that results in the merger of two or more Medicare-enrolled entities into a new entity is a consolidation and is also a CHOW. To illustrate, the owner of Hospital A decides to purchase Hospital B and then combine the two into a new business entity with a new tax id number (Hospital C). Hospital C will have its own CCN and provider agreement. If the purchaser of Hospital B accepts assignment of Hospital B's provider agreement, the buyer and seller's CCNs will be retired. If the purchaser/owner of Hospital A does not accept assignment of Hospital B's provider agreement, Hospital C must enroll as a new applicant in the Medicare program.

SAs should refer to SOM 2779F related to the assignment of CCNs when there has been a CHOW.

NOTE to MACs: Although the CMS-855A separates transactions into "Change of Ownership/CHOW", "Acquisition/Merger," and "Consolidations," all three transactions fall within the category of Medicare CHOWs under 42 CFR § 489.18 and result in the assignment of the Medicare provider agreement to a new owner. *See* PIM §§ 10.6.1.1; 10.6.22.

CMS Certification Numbers (CCNs) & Effective Dates

Impact on the CCN After a Merger of Two Providers:

- Surviving Hospital CCN remains while the other Hospital CCN is retired upon the merger of two hospitals.

- If two or more certified entities continue to operate separately, they will continue to have a separate provider agreement/supplier approval, and the CCNs of each entity will remain unchanged (see Chapter 2, Section 2779F of the SOM)

- In situations where a change of ownership does not result in a CHOW of an individual provider or supplier, the provider's Medicare provider agreement or supplier's Medicare supplier approval will remain in effect, and the CCN used to track the Medicare agreement will not be changed.

- When an individual provider or supplier undergoes a CHOW and the new owner combines the provider/suppliers into another Medicare-participating entity, the CCN of the surviving provider/supplier remains while the other CCN of the other provider/supplier will be retired.

Part II –Administrative Changes

Many enrollment certification actions are not CHOWs. These situations are generally when a provider/supplier changes names, not due to a CHOW or an administrative update to the provider agreement.

Administrative Changes –Hospitals, Psychiatric Hospitals, Transplant Programs:

Hospitals:

- **Mergers:** When two or more hospitals merge, the SA ascertains whether to continue to certify the hospitals separately or to certify them as a single hospital (i.e., a hospital with the main campus and an additional location).
- **Multiple Locations:** Each location of a single hospital must meet the applicable CoPs. A certification of non-compliance at the CoP level at any hospital location affects the hospital's certification as a whole.
- **Locations Across State Lines:** Regulations at §413.65(e)(3)(vii) allow provider-based locations across State lines when consistent with the laws of each adjacent state. There are many hospitals with outpatient departments located in another state when the location is near state lines. The concern arises when the SA/AO must conduct a FULL survey. Note, for non-deemed hospitals, SA surveyors in one state cannot go into another state. Therefore, there should be a reciprocal agreement between the States when a provider has off-campus departments located in another state.
    - A State's licensing laws apply only to those locations within the State, not those locations in another State.
    - The SA for which the "main campus of the Hospital" is located determines which SA has overall survey responsibility. The survey must be one survey, not separate or serial surveys. Therefore, the SA location of the "main location of the hospital" will reconcile survey information from the other location(s) and send only one recommendation to the MAC.
    - For deemed hospitals with locations across state lines, the AO will send the recommendation to the MAC (per the steps in the general SOP) as no reciprocal agreement is needed since AOs are national in scope.

- **Swing-Beds:** "Swing-bed" is a reimbursement term that means the care and reimbursement for the care of a patient in a small rural hospital "swings" from acute care to post hospital skilled nursing care (SNF). A swing-bed hospital means a hospital in Medicare that has an approval from CMS to provide post hospital SNF care and meets the requirements specified in §482.66 for a hospital. To retain swing bed status, the combined hospital bed count must be under 100, and the hospital's main campus is located in a rural area (see SOM Chapter 2). The SA will make this determination.
    - The request to retain swing-bed status can be initiated on the provider's letterhead stationery and sent to the SA. Acknowledgement and request for further information can be sent from the SA to the provider in a letter, see SOM Exhibit 81. With a merger, the new Owner must specify the intent to keep or voluntarily terminate swing-beds.
    - Certification to provide swing-beds is an approval separate from the certification to operate as a hospital. Swing-beds are treated as initial certifications because new unit is being added to facility.
    - When a survey of swing-beds is completed, the SA will make the determination. Information on swing-bed approval is communicated via the CMS 1539.
    - If the swing-beds are voluntary terminated, that action does not affect the continuing operation of the provider as a hospital. It terminates the approval to operate and receive reimbursement for the swing-beds. CPI/PEOG will process swing-bed voluntary terminations and adjust the CCN of the hospital to remove the identifier.
    - Swing-beds receive an identifier within the CCN. See above general CCN guidance.

Psychiatric Hospitals:

- **Distinct Part**: The distinct part provisions of the law are designed to permit the participation of those identifiable sections of psychiatric hospitals that are adequately staffed, supervised, and equipped to provide active treatment on a continuing basis. The distinct participating part must meet the hospital CoPs and the two special CoPs and have appropriate treatment services available. The provisions for certification of distinct parts of psychiatric hospitals apply only where the entire institution is primarily for treating mental illness. Thus, a general hospital's psychiatric wing or building or a large medical center or complex may not be certified as a "distinct part psychiatric hospital," but are included in the certification of the institution of which they are an integral part.

Transplant Programs: No relocations, address changes, etc., are reviewed as the transplant programs are attached to the hospital. Administrative changes related to location changes do not occur in transplant programs because the administrative change can only be at the hospital level, not at the program level.

If any provider decides to terminate voluntarily, the SA, CPI/PEOG, and the MACs will follow the procedures outlined in the Voluntary Termination SOP.

Part III –Initial Certification and Enrollment

All responsible parties will follow the general SOP instructions for initial enrollment and certification of hospitals, psychiatric hospitals, and transplant programs. The below highlights additional steps or nuances required for completing the initial certification.

Hospitals: Hospital Worksheet must be completed to input into the national database system by the SA. The SA is responsible for obtaining this since most AOs are not required to use this form.

Transplant Programs: Initial certification processes will follow Part III, Section III of the general SOP. Once the MAC notifies the SA of its approval of the revised CMS-855A, a survey may be scheduled. In addition to the required documentation (e.g., CMS 855A), the SA must include the

Transplant Program Quarterly Report (TPQR) within the initial certification package. During the transplant program survey process, the SA surveyors review compliance with the transplant program and general hospital regulations. For CMS to make a compliance determination with §482.80, the applicant must have submitted sufficient data to the SRTR for CMS to review. The TPQR must be included in the initial certification package. However, it is only used by the SA.

> **There is no MAC review/action required for the TPQR report.** Once transplant program approval is completed, the SA will forward a form CMS-1539 to the MAC. If the applicant transplant program is found to comply with the CoPs, it is assigned a CCN by CPI/PEOG per the SOP process. The program will not be issued a separate provider agreement (transplant programs fall under the hospital agreement).

Part IV –Important Reminders & Resources

Important Reminders Resources

- A Critical Access Hospital (CAH) may continue to participate in Medicare by converting to a hospital. If the CAH chooses to convert to a hospital, the CAH would need to submit to the MAC another Form CMS-855 to terminate their CAH enrollment along with a separate Form CMS-855 to enroll as a hospital. **Conversions will continue to follow the existing process and not be transitioned as part of the certification work at this time.**

Additional Resources

- CHOW, Administrative Changes; Relocations & Initials- General SOP
- SOM Chapter 2