PLEASE NOTE: The attached information is intended as a general overview of frequently requested information on certification resources and activities/processes. This serves as a basic introduction to Medicare certification and is not intended as a comprehensive manual.

Links to CMS Website Resources

Electronic Code of Federal Regulations (CFR)
http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?sid=614cb89fc17db8dae88af84c6b174bf1&c=ecfr&tpl=/ecfrbrowse/Title42/42tab_02.tpl

State Operations Manual (SOM)
http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS1201984&intNumPerPage=10

Survey & Certification (S&C) Letters
http://www.cms.gov/SurveyCertificationGenInfo/PMSR/list.asp

Interpretive Guidelines (IG) – Appendices
http://www.cms.gov/manuals/downloads/som107_Appendicestoc.pdf

Exhibits – Model Letters
http://www.cms.gov/manuals/downloads/som107c09_exhibitstoc.pdf
Please refer to Exhibit 63 (revised 04/09/2010) for a comprehensive listing of documents in Initial certification packets including initial denials.

Office for Civil Rights (OCR)
http://www.hhs.gov/ocr/civilrights/resources/providers/medicare_providers/index.html

Direct Provider to OCR Website and have them complete the following and return to the State Agency unless they have a "Civil Rights Corporate Agreement"

- "Data Request Checklist" (Form OMB No. 0990-0243) along with their supporting P&Ps
- "Assurance of Compliance" (Form HHS-690) ask provider to sign 2 copies

Refer to S&C 09-57 issue 09/11/2009 and revised 03/19/2010 for list of providers/suppliers who need to go through OCR clearance. List includes Corporate Agreement holders.

CMS Website
http://www.cms.gov/

CMS Forms
http://www.cms.gov/CMSForms/CMSForms/list.asp#TopOfPage

CMS-approved Accrediting Organization (AO) contact information
http://www1.cms.gov/SurveyCertificationGenInfo/Downloads/AOContactInformation.pdf
The following providers/suppliers can achieve "deemed" status through an AO: Hospitals, Critical Access Hospitals, Home Health Agencies, Hospices, and Ambulatory Surgery Centers

QIES and CASPER Reports
https://web.qiesnet.org/qiestosuccess/

List of Acronyms used

AO Accreditation Organization
CAH Critical Access Hospital
C&T Certification & Transmittal
CCN CMS Certification Number (the first 2 numbers represent the State, for ex., 50 =WA)
CFR Code of Federal Regulations
CHOW Change of Ownership
CMS Centers for Medicare & Medicaid Services
DPU Distinct Part Unit (refers to Psych and/or Rehab units in a CAH)
FI Fiscal Intermediary
HIB Health Insurance Benefit Agreement
LSC Life Safety Code
OASIS Outcome and Assessment Information Set
PoC Plan of Care
PPS-Excluded Unit Prospective Payment System-Excluded Unit (refers to Psych and/or Rehab units in a Hospital)
RO Regional Office
SA State Agency

CERTIFICATION (from SOM Chapter 1)

The Social Security Act (the Act) mandates the establishment of minimum health and safety and CLIA standards that must be met by providers and suppliers participating in the Medicare and Medicaid programs. The Secretary of the Department of Health and Human Services (DHHS) has designated CMS to administer the standards compliance aspects of these programs.

Medicare is a Federal insurance program providing a wide range of benefits for specific periods of time through providers and suppliers participating in the program. **Providers**, in Medicare terminology, include patient care institutions such as hospitals, critical access hospitals (CAHs), hospices, nursing homes, and home health agencies (HHAs). **Suppliers** are agencies for diagnosis and therapy rather than sustained patient care, such as laboratories, clinics, and ambulatory surgery centers (ASCs). The Act designates those providers and suppliers that are subject to Federal health care quality standards.

Certification is when the SA officially recommends its findings regarding whether health care entities meet the Act's provider or supplier definitions, and whether the entities comply with

standards required by Federal regulations. State agencies do not have Medicare determination-making functions or authorities; those authorities are delegated to CMS' RO. State agency certifications are the crucial evidence relied upon by the ROs in approving health care entities to participate in Medicare and CLIA. Recertifications are performed periodically by the SAs.

"DEEMED"

Section 1865(b)(1) of the Social Security Act (the Act) permits providers and suppliers "accredited" by an approved national accreditation organization (AO) to be exempt from routine surveys by State survey agencies to determine compliance with Medicare conditions. Accreditation by an AO is voluntary and is not required for Medicare certification. Section 1865(b)(1) of the Act provides that if the Secretary finds that accreditation of a provider entity by a national accreditation body demonstrates that all applicable conditions are met or exceeded, the Secretary may deem those requirements to be met by the provider or supplier. Before permitting deemed status for an AO's accredited provider entities, the AO must submit an application for CMS review and approval. The following five provider/supplier types are eligible for "deemed" status through an AO:

- Hospitals
- Critical Access hospitals
- Home Health Agencies
- Hospices
- Ambulatory Surgery Centers

AMBULATORY SURGERY CENTER (ASC)

- 42 CFR § 416 Subpart A, B and C
- SOM 2210
- Appendix L

ASC Documents	**Initial**	**CHOW**
C&T (CMS 1539)	✓	✓
855B	✓	✓
FI recommendation on 855B	✓	✓
Health Insurance Benefit Agreement – 2 signed copies (CMS-370)	✓	✓
Request to establish Eligibility (CMS-377 and 378)	✓	✓
Either Health & LSC surveys through State(2567s, 670 hours, PoC if deficiencies, etc) **OR** Awarded "deemed" accreditation through an AO	✓	

Note: OCR clearance paperwork not required for ASCs

CRITICAL ACCESS HOSPITAL (CAH)

- 42 CFR § 485 Subpart F
- SOM 2254 - 2262
- Appendix W

CAH Documents	Initial	CHOW
C&T (CMS 1539)	✓	✓
855A	✓	✓
FI recommendation on 855A	✓	✓
Health Insurance Benefit Agreement – 2 signed copies (CMS-1561)	✓	✓
Hospital / CAH Database Worksheet (Exhibit 286))	✓	✓
Either Health and LSC surveys through State (2567s, 670 hours, PoC if deficiencies, etc) **OR** Awarded "deemed" accreditation through an AO	✓	
Letter of support from State Office of Rural Health	✓	
Either OCR paperwork OR evidence of Civil Rights Corporate Agreement	✓	✓

Note: A CAH must first be Medicare-certified as a Hospital. And located in a rural area. CAH's can have no more than 25 Medicare –certified beds unless they have DPUs.

COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY (CORF)

- 42 CFR § 485 Subpart B and 42 CFR 410 Subpart D
- SOM 2360 – 2366
- Appendix K

CORF Documents	Initial	CHOW
C&T (CMS 1539)	✓	✓
855A	✓	✓
FI recommendation on 855A	✓	✓
Health Insurance Benefit Agreement – 2 signed copies (CMS-1561)	✓	✓
Request to establish Eligibility (CMS-359)	✓	✓
Health survey (2567s, 670 hours, PoC if deficiencies, etc)	✓	
CORF Survey Report (CMS-360)	✓	
Either OCR paperwork OR evidence of Civil Rights Corporate Agreement	✓	✓

END STAGE RENAL DISEASE (ESRD)

- 42 CFR § 494 Subpart A-D
- SOM 2270 – 2278, 2779J, and 2280-2287

- Appendix H (the CMS-Online version has not been updated with the New ESRD Regulations and Surveyor Guidance, so refer to S&C 09-01 issued 10-03-2008)

ESRD Documents	Initial	CHOW
C&T (CMS 1539)	✓	✓
855A	✓	✓
FI recommendation on 855A	✓	✓
ESRD Facility Survey Report (CMS-3427)	✓	✓
Health survey (2567s, 670 hours, PoC if deficiencies, etc)	✓	
Certificate of Need in States where it is required	✓	

Note: there is no OCR clearance paperwork and no Health Insurance Benefit Agreement

ESRD Expansion of Services

SOM 2278D [A facility must complete Part I of the Form CMS-3427A when it requests expansion of the number of stations or desires to change its services, including reuse. A SA survey is required if the facility has not been surveyed in more than 6 months, or if substantial changes have been made.]

ESRD Expansion of Services Documents	ESRD Survey within past 6 months	Last ESRD survey > than 6 months ago
C&T (CMS 1539)	✓	✓
ESRD Facility Survey Report (CMS-3427 Part 1)	✓	✓
ESRD survey		✓

Note: No 855A required

HOME HEALTH AGENCY (HHA)

- 42 CFR § 484
- SOM 2180 – 2201.19
- Appendix B

HHA Documents	Initial	CHOW
C&T (CMS 1539)	✓	✓
855A	✓	✓
FI recommendation on 855A	✓	✓
Health Insurance Benefit Agreement – 2 signed copies (CMS-1561)	✓	✓
Home Health Agency Survey and Deficiencies Report (CMS-1572)	✓	✓
Either Health survey through State (2567s, CMS-1515 Home Health Functional Assessment Modules A-B-C-D-E-F, 670 hours, PoC if deficiencies, etc) **OR** Awarded "deemed" accreditation through an AO	✓	
Either OCR paperwork OR evidence of Civil Rights Corporate Agreement	✓	✓

HHA applicant must demonstrate successful OASIS data submission prior to the initial certification/accreditation survey

HOME HEALTH AGENCY REQUESTS TO ADD A BRANCH
Meet State requirements

HHA Branch Documents	Branch
C&T (CMS 1539)	✓
855A	✓
FI recommendation on 855A	✓
Documentation that demonstrates how SOM 2182.4A met	✓

The RO will assign the Branch Identifier once HHA Branch requirements are met; the Branch Identifier is used for OASIS submission

HOSPICE

- 42 CFR § 418 Subpart A-D
- SOM 2080-2089 (the CMS-Online version has not been updated with the new Hospice Certification Process, so refer to S&C 09-58 issued 09/18/2009)
- Appendix M (the CMS-Online version has not been updated with the New Hospice Regulations and Surveyor Guidance, so refer to S&C 09-19 issued 01/02/2009)

Hospice Documents	Initial	CHOW
C&T (CMS 1539)	✓	✓
855A	✓	✓
FI recommendation on 855A	✓	✓
Health Insurance Benefit Agreement – 2 signed copies (CMS-1561)	✓	✓
Hospice Request for Certification (CMS-417)	✓	✓
Either Health survey through State (2567s, CMS-643 Hospice Survey and Deficiencies Report, 670 hours, PoC if deficiencies, etc) **OR** Awarded "deemed" accreditation through an AO	✓	
Either OCR paperwork OR evidence of Civil Rights Corporate Agreement	✓	✓

Note: If Hospice will provide "Inpatient care" directly, then a LSC survey must be done in addition to surveying for compliance with regulations at 42 CFR 418.110

HOSPICE Requests to add "Multiple Location"
Must meet State requirements

HOSPICE "Multiple Location" Documents	Multiple Location

C&T (CMS 1539)	✓
855A	✓
FI recommendation on 855A	✓
Documentation that demonstrates how SOM 2088 met	✓

Note: If the Hospice is "deemed" through an AO, it should notify the AO of the proposed "multiple location". There is no unique "multiple location" identifier/number assigned by the RO.

HOSPITAL

- 42 CFR § 482
- SOM 2020 – 2054
- Appendix A

Hospital Documents	**Initial**	**CHOW**
C&T (CMS 1539)	✓	✓
855A	✓	✓
FI recommendation on 855A	✓	✓
Health Insurance Benefit Agreement – 2 signed copies (CMS-1561)	✓	✓
Hospital / CAH Database Worksheet (Exhibit 286))	✓	✓
Either Health and LSC surveys through State (2567s, 670 hours, PoC if deficiencies, etc) **OR** Awarded "deemed" accreditation through an AO	✓	
Either OCR paperwork OR evidence of Civil Rights Corporate Agreement	✓	✓

OUTPATIENT PHYSICAL THERAPY – SPEECH PATHOLOGY (OPT-SP)

- 42 CFR § 485 Subpart H
- SOM 2290 - 2306
- Appendix E

OPT Documents	**Initial**	**CHOW**
C&T (CMS 1539)	✓	✓
855A	✓	✓
FI recommendation on 855A	✓	✓
Health Insurance Benefit Agreement – 2 signed copies (CMS-1561)	✓	✓
Request to Establish Eligibility (CMS 1856)	✓	✓
Survey through State (2567s, 670 hours, OPT-SP Survey report CMS-1893), PoC if deficiencies, etc)	✓	
Either OCR paperwork OR evidence of Civil Rights Corporate	✓	✓

Agreement		

IMPORTANT: On an annual basis, SA sends to each OPT a copy of "Identification of Extension Locations of OPT/OSP Providers" (CMS-381). Please refer to SOM 2300 for more detailed instructions. The SA will forward the annual summary report to the RO. The RO will assign and enter the Extension Location Identifiers into ASPEN.

PORTABLE X-RAY

- 42 CFR § 486 Subpart C
- SOM 2240 - 2424
- Appendix D

Portable X-Ray Documents	Initial	CHOW
C&T (CMS 1539)	✓	✓
855B	✓	✓
FI recommendation on 855B	✓	✓
Request to Establish Eligibility (CMS-1880)	✓	✓
Health survey (2567s, 670 hours, Portable X-Ray Survey Report CMS-1882, PoC if deficiencies, etc)	✓	
Certificate of Need in States where it is required	✓	

Note: there is no OCR clearance paperwork and no Health Insurance Benefit Agreement

PROVIDER-BASED and PRACTICE LOCATIONS

- 42 CFR § 413.62
- SOM 2004
- There is no Appendix

Hospitals and CAHs can request that certain outpatient services/departments be designated as provider-based. Being designated as provider-based to either a hospital or CAH essentially means that the entity is owned and operated by a hospital or CAH and is sufficiently integrated with the hospital or CAH, that it functions as an extension of the hospital or CAH. Providers can submit an 855A and/or a Self Attestation. A key component of the approval process is confirming that the location has been added to the Hospital's or CAH's license.

Provider-based and Practice Location Documents	Practice Location
C&T (CMS 1539)	✓
855A and/or Provider-based Self Attestation	✓
FI recommendation on 855A or Self Attestation	✓
Location added to the Hospital's or CAH's license	✓

PROSPECTIVE PAYMENT EXCLUDED (PPS) UNITS

42 CFR § 412 Subpart B
SOM 3100 – 3112
Psychiatric Unit Criteria Work Sheet (CMS-437)

Rehabilitation Unit Criteria Work Sheet (CMS-437A)
Rehabilitation Hospital Criteria Worksheet (CMS-437B)

PPS-Excluded Unit Documents	Initial	Annually	CHOW
Self-Attestation	✓	✓	Hospital provider agreement is accepted.
C&T (CMS 1539)	✓	✓	
Psych/Rehab Criteria Work Sheet	✓	✓	
Rehab Hospital Criteria Work Sheet	✓	✓	See hospital.

Note: On an annual basis, SA sends to hospitals/CAHs the applicable PPS-excluded Unit criteria work sheet and Attestation and asks hospital to complete and return to SA. SA attaches the Work Sheet and Attestation to the C&T and forwards to the RO.

Note: Distinct Part Units are in critical access hospitals and follow the same rules as PPS-excluded inpatient rehab/psych units, with one exception: They are limited to no more than 10 beds for each of the units. These beds are not counted in their overall limit of 25 beds.

RURAL HEALTH CLINICS (RHC)
42 CFR § 491 Subpart A and 42 CFR § 405 Subpart X (addresses services covered))
SOM 2240 - 2249
Appendix G

RHC Documents	Initial	CHOW
C&T (CMS 1539)	✓	✓
855A	✓	✓
FI recommendation on 855A	✓	✓
Health Insurance Benefit Agreement – 2 signed copies (CMS-1561A)	✓	✓
Request to Establish Eligibility (CMS 29)	✓	✓
Survey through State (2567s, 670 hours, RHC Survey report CMS-30), PoC if deficiencies, etc)	✓	
To be completed by Provider-Based RHCs ONLY Either OCR paperwork OR evidence of Civil Rights Corporate Agreement.	✓	✓

Note: RHC's have their own unique Health Benefit Agreement – CMS 1561A
If RHC is free-standing, no OCR clearance required.

VALIDATION –SAMPLE (SOM 3242 – 3257)
The Sample Validation survey process is designed to evaluate the premise that a deemed provider/supplier that receives accreditation by a nationally approved accreditation organization under§1865 of the Act is, in fact, meeting Medicare health and safety requirements. The SA conducts validation surveys of deemed provider types in accordance with established procedures to ensure a fair basis for evaluating the effectiveness of approved accreditation organizations.

CO selects a representative sample of accredited provider/suppliers for the SA to conduct a validation survey and forwards this listing to the ROs. The validation survey covers all the Conditions that are deemed to be met by virtue of accreditation by a nationally recognized accreditation organization.

The SA shall conduct the Sample Validation survey within a 60-day timeframe from the end date of the AO's accreditation survey.

The SA should enter the 2567(s) and 670 hours into ASPEN along with completing the other Tabs within the Validation Cert Kit.

The SA shall return the following documents to the RO after Sample Validation survey is completed:

- Exhibit 287 signed by the provider/supplier [*Authorization by deemed provider/supplier selected for accreditation organization validation survey*]
- Completed initial application worksheets/forms
    - ❖ Hospitals/CAHS → Hospital/CAH Database Worksheet (Exhibit 286)
    - ❖ Home Health Agency → CMS Form 1572
    - ❖ Hospice → CMS Form 417
    - ❖ ASC → CMS Forms 377 and 378

The RO will mail the survey results to the provider and then complete the ASPEN upload of the Validation Cert Kit.