

Licensure, Certification, and Surveys  
Non-Long Term Care Learning Activity

Item	Description
Objective:	<ul style="list-style-type: none"> <li>• The surveyor will identify the differences between state licensure and Federal certification of facilities.</li> <li>• The surveyor will describe the interactive relationships between his or her state CMS Regional Office (RO), and CMS Central Office (CO).</li> </ul>
Materials Needed:	Licensure, Certification, and Surveys Information Sheet and Quiz, and a timer
Total Time for Activity:	30 minutes* (*Activity times are highly dependent on class size and dynamics. The time given is approximate.)
Prior to Class:	Print enough quizzes and information sheets to distribute to surveyors.

Steps:	Preceptor Instructions:	Activity Time:
1.	Distribute one Licensure, Certification, and Surveys Information Sheet and one Quiz to each surveyor face down. If the group is large enough, divide the surveyors into teams. Explain the activity. Rules: Surveyors are not to view the information sheet or quiz questions prior to the timer starting. When the preceptor starts the timer, the surveyors have ten minutes to answer as many questions as possible using the information sheet.	10 min.
2.	Set the timer for ten minutes. When ready, give the surveyors permission to start the quiz. When the ten minutes expire, instruct surveyors to stop answering questions.	10 min.
3.	Debrief by reviewing the correct answers to each question. Identify the surveyor or the team with the most correct answers.	5 min.
4.	Answer any questions the surveyors may have about licensure, certification, and surveys.	5 min.

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Licensure, Certification, and Surveys Information Sheet

Item	State Survey Agency (SA) Licensure	Federal Certification
Source of Authority	State Law and Regulations on Health Care Facility Licensure	Federal Law and Regulations on Medicare and Medicaid
Law	<p>Enacted by Legislature, signed by governor</p> <p>Generally not “self-implementing”—i.e., language of the law is broad and requires more detailed interpretation through regulation</p>	<p>Social Security Act, Title 18, Medicare, &amp; Title 19, Medicaid</p> <p>Enacted by Congress, signed by President</p> <p>Often not “self-implementing”—i.e., language of the law is broad and requires more detailed interpretation through regulation. Typically, the statutory definitions of the types of Medicare providers and suppliers include a provision for such other standards as the Secretary may require.</p>
Mandatory or voluntary?	Mandatory—if state law requires a license, the health care facility may not operate without a license	<p>Voluntary:</p> <ul style="list-style-type: none"> <li>• Participation in Medicare and Medicaid by a health care provider or supplier is voluntary.</li> <li>• The provider/supplier facility voluntarily signs an agreement with the Medicare and/or Medicaid program to comply with all applicable program requirements.</li> <li>• For all providers, and some types of suppliers, the facility must be certified as complying with the applicable Conditions of Participation, Conditions for Coverage, or Conditions for Certification.</li> </ul>
Types of	Failure to comply could include	Enforcement (non-LTC): If substantial

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sanctions	monetary penalties, curtailment of operations, license suspension, and license revocation. Health care facilities with a suspended or revoked license may not conduct any business.	noncompliance of a certified provider or supplier is not corrected in a timely manner, the agreement with the provider or supplier is terminated, meaning its Medicare and/or Medicaid payments cease.
Regulation adoption process	<p>SA regulation adoption process varies from state to state. In general:</p> <ol style="list-style-type: none"> <li>1. Proposed regulations developed within the agency responsible for health care facility licensure</li> <li>2. Proposed regulations published for public comment (In some states, before publication an appointed board must approve for initial publication)</li> <li>3. Final rule developed within the agency responsible for health care facility licensure</li> <li>4. Final rule published (In some states, before publication an appointed board must approve for final publication.)</li> </ol>	<p>Federal Medicare/Medicaid regulation process within the Department of Health and Human Services (DHHS):</p> <ol style="list-style-type: none"> <li>1. CMS develops new or amended rule, which undergoes clearance within CMS, the DHHS Office of General Counsel, any additional DHHS agencies, and the Office of Management and Budget</li> <li>2. After the rule is cleared by all of the above, Notice of Proposed Rulemaking (NPRM) is signed by the CMS Administrator and DHHS Secretary and published in the Federal Register to solicit comments from the public.</li> <li>3. Comment Period is generally a minimum of 60 days.</li> <li>4. CMS reviews comments and develops draft final rule which goes through the same internal clearance process as the NPRM.</li> <li>5. Regulations are published as final rule in the Federal Register, generally effective 60 days after publication.</li> <li>6. Rules are incorporated into the Code of Federal Regulations (CFR).</li> </ol>
Interpretive	Varies by state as to whether	Federal rules are often intentionally

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Guidance	there is a role for interpretive guidance. In some states, the regulations must be very detailed and guidance is not permitted or necessary.	<p>broad, to avoid need for frequent amendment. As a result, CMS interprets the regulations in the State Operations Manual (SOM) to assist SA and RO staff with determining compliance with the regulations.</p> <p>This “subregulatory” guidance can be updated by CMS without formal rulemaking, but must always be based on the language to the current rules.</p> <p>The SOM also contains detailed survey process guidance to implement the Social Security Act Section 1864 agreements between CMS and SAs.</p> <p>SAs and ROs use the SOM in certification and survey activities.</p>
Applying for Licensure vs. Certification	State establishes the process to be used to apply for a license; varies by state	<p>Health care facilities subject to certification must:</p> <ol style="list-style-type: none"> <li>1. Submit an application to enroll in Medicare either online or via paper application to their Medicare Administrative Contractor (MAC). Facilities enrolling in Medicaid follow the application process specified by the State Medicaid Agency.</li> <li>2. The MAC notifies the applicant, the SA, and the RO whether it is recommending enrollment.</li> <li>3. The applicant also contacts the SA for a certification application packet.</li> <li>4. Applicant submits all certification application documents to the SA.</li> </ol>

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		5. Only after the MAC has made its recommendation, the SA (or an accrediting organization, for facilities seeking deemed status) conducts a survey.  6. The applicant is certified only if it is in substantial compliance with all applicable regulations. Various scenarios possible based on survey findings.  7. The RO reviews the survey report recommending certification and other certification documents and makes the determination whether to certify the applicant and the effective date of its Medicare provider/supplier agreement.
Investigation of compliance	State law and regulations determine which agency enforces licensure standards and by what means	CMS entered into a Section 1864 Agreement with each state, the District of Columbia, Puerto Rico, and certain U.S. territories.  42 CFR Part 488 governs survey and enforcement processes, as supplemented by the SOM and documents such as the Survey and Certification Administrative and Policy memoranda.
Survey frequency	Frequency is determined by state licensing regulations and the state budget.	Annually, under the following conditions:  1. The annual Mission and Priority Document establishes SA survey workload and priorities for the Federal fiscal year.  2. Federal government matches

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		<p>Medicaid funding, but Medicare surveys and certification work is paid for entirely from Medicare money. Congress determines the size of this funding each year.</p> <p>3. Medicare monies also fund training, equipment, and SA overhead expenses.</p> <p>4. Federal surveyors from the RO must conduct a validation survey of the SA’s Federal survey work for five percent of the long-term care facilities in the state and one percent of other providers annually.</p> <ul style="list-style-type: none"> <li>• Federal surveyors can survey within 30 days after state surveyors or accompany state surveyors on their surveys. The purpose is to monitor the SA and assess the training of that agency’s surveyors.</li> </ul>
Survey geographic scope	State policies and procedures determine if all locations included in the license are surveyed.	All locations covered under the Medicare provider agreement, unless directed otherwise, are included. Some types of providers are allowed to operate under one agreement in multiple locations.

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**Licensure, Certification, and Surveys Quiz**

1. Who makes the licensing regulations for health care organizations?
2. \_\_\_\_\_ makes the certification regulations for health care organizations.
3. Who proposes certification regulations?
  - a. State Survey Agency
  - b. Legislators
  - c. Congress
  - d. CMS Regional Office
4. Who votes and approves health care facility licensing regulations?
5. Who votes to approve certification regulations?
  - a. State Survey Agency
  - b. Legislator
  - c. Congress
  - d. CMS Regional Office
6. After a law is enacted, the period of comment is a minimum of \_\_\_\_\_ days.
  - a. 10
  - b. 30
  - c. 60
  - d. 90
7. Final certification rules are signed by the \_\_\_\_\_.
  - a. Department of Health and Human Services (DHHS)
  - b. Office of Management and Budget (OMB)
  - c. Centers for Medicare & Medicaid Services (CMS)
  - d. State Legislature
8. Authority to enforce certification laws is delegated to \_\_\_\_\_.
  - a. Department of Health and Human Services (DHHS)
  - b. Office of Management and Budget (OMB)
  - c. Congress
  - d. Centers for Medicare & Medicaid Services (CMS)

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9. True or false: Certification is voluntary.
10. True or false: Licensure is voluntary.
11. Which entity must agencies first contact if they wish to initiate certification?
  - a. Long-term Care Facility
  - b. State Survey Agency
  - c. Regional Office
  - d. Centers for Medicare & Medicaid Services (CMS)
12. The state's \_\_\_\_\_ appoints an agency to conduct surveys and certifications.
  - a. Governor
  - b. Lieutenant Governor
  - c. Regional Office
  - d. Senator
13. The \_\_\_\_\_ budget determines the frequency of State Agency licensure surveys.
  - a. Organization
  - b. State Agency
  - c. State
  - d. Federal
14. Federal surveyors can conduct validation surveys \_\_\_\_\_ days after an SA survey in the long-term care facilities.
  - a. 6
  - b. 15
  - c. 30
  - d. 45

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**Licensure, Certification, and Surveys Quiz Answer Sheet**

1. Who makes the licensing regulations for health care organizations?

*Answer: The state legislature makes the licensing regulations for health care organizations.*

2. Congress makes the certification regulations for health care organizations.

3. Who proposes certification regulations?

- a. State Survey Agency
- b. Legislators
- c. Congress
- d. CMS Regional Office

4. Who votes and approves health care facility licensing regulations?

*Answer: State Legislatures, and then signed by the Governor.*

5. Who votes to approve certification regulations?

- a. State Survey Agency
- b. Legislators
- c. Congress
- d. CMS Regional Office

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9. True or false: Certification is voluntary.

*Answer: True. Certification is voluntary for entities that wish to receive money for treating Medicare- and Medicaid-eligible individuals.*

10. True or false: Licensure is voluntary.

*Answer: False. Licensure is mandated for pre-determined health care organizations and entities by the state legislature.*

11. Which entity must agencies first contact if they wish to initiate certification?

- a. Long-term Care Facility
- b. State Survey Agency
- c. Regional Office
- d. Centers for Medicare & Medicaid Services (CMS)

12. The state's \_\_\_\_\_ appoints an agency to conduct surveys and certifications.

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- b. Lieutenant Governor
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