



Department
of Health

Waiver and Equivalency **Submission Guidelines for** **Nursing Home Providers**

Purpose

To inform nursing home providers on:

1. The application of waivers to waive State and Federal code requirements.
2. The waiver process as required by State and Federal regulations and guidance.
3. Expectations for providers that request a waiver.

Overview

1. Prescriptive Code, Equivalency, and Waivers
2. Waiver and Equivalency Submission Guidelines
 - When a waiver is used, types of waivers
 - How to submit a waiver request
3. Enforcement with Waivers in Progress
4. Waiver Determinations
 - If more information is needed
 - If Approved or Denied
5. Post-Approval Facility Obligations

1. Prescriptive Code, Equivalency, and Waivers

Not Meeting Prescriptive Code

When a facility is cited for not having met the regulatory requirements, as documented on a Statement of Deficiency (SOD), facilities are required to make every effort to do the work necessary to correct the deficiency.

Not Meeting Prescriptive Code

For a Federal citation:

Refer to CMS Regulations and Guidance including **but not limited to** Centers for Medicare and Medicaid (CMS) State Operations Manual, Ch 7 – Survey and Enforcement Process:

§ 7014 – Special Waivers Applicable to Skilled Nursing Facilities and Nursing Facilities

§ 7410 – Life Safety Code Enforcement Guidelines for Skilled Nursing Facilities and Nursing Facilities

1. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984>

Achieving Compliance by Equivalency

Specific to Federal Life Safety Code (LSC):

If the facility is unable to come into code compliance for a specific citation/tag, **the facility may choose to use an alternative system, method, or device to reach a level of safety equivalent or superior** to that achieved by the 2012 edition of the National Fire Protection Association (NFPA) 101 – *Life Safety Code (the Code)*.

This option is called *Equivalency*.

Achieving Compliance by Equivalency

Technical documentation to prove equivalency must be submitted through the review process, and each method must be approved by the Authority Having Jurisdiction. There are several ways of reaching equivalency to provisions of *the Code*.²

Some alternative systems or methods include:

- The *Fire Safety Evaluation System (FSES)*, which is found in the 2013 edition of NFPA 101A, *Guide on Alternative Approaches to Life Safety*, or
- Performance-based design, which is found in Chapter 5 of *the Code*.

The use of the FSES is the most common method.²

². https://qsep.cms.gov/pubs/CourseMenu.aspx?cid=0CMSBLSC_ONL

Achieving Compliance by Equivalency

FSES Training is available through CMS' QSEP platform

Training plan description:

The FSES training is intended to establish surveyor knowledge of the FSES process as it pertains to health care occupancies (HCO). This training focuses on the FSES as an alternative survey approach for health care facilities that cannot prescriptively comply with the requirements of the LSC. The FSES is an approach that allows facilities to demonstrate equivalent safety measures to the LSC minimum requirements, without meeting all LSC requirements directly. As Medicare Conditions of Participation require compliance with the LSC, this training builds on previous trainings concerning the LSC as it applies to health care facilities.³

3. https://qsep.cms.gov/pubs/CourseMenu.aspx?cid=0CMS_FSES-HCSTC

Achieving Compliance by Equivalency

What is the purpose of an FSES?

As CMS describes in the FSES training:

- An FSES evaluation is performed to determine whether or not the facility's fire protection features are sufficient to provide a level of protection equivalent to that achieved by compliance with the LSC.³ The evaluation is a building-wide assessment of current conditions, organized and evaluated by zones.
- An FSES evaluation measures various safeguards and assigns a quantitative, numerical value to each safety parameter and risk parameter. The parameter values are then compared to mandatory values to determine whether or not equivalency with the LSC has been demonstrated. If an FSES evaluation determines an equivalent level of compliance, the facility is said to have 'demonstrated equivalency.'³

Achieving Compliance by Equivalency

CMS considers a health care facility that provides equivalent safety, as measured by the FSES, to be in compliance with the LSC, and it can be certified for participation in Medicare and Medicaid.³

How does a facility ensure the FSES report is complete and scored correctly?

Facilities may elect to commission a design professional to provide the building evaluation for the NFPA 101A-2013 FSES report. Refer to the 2013 edition of *NFPA 101A Handbook Commentary*⁴ for scoring instructions and explanations.

4. <https://www.nfpa.org/codes-and-standards>

Achieving Compliance by Equivalency

If the facility elects to come into equivalency for a cited Federal regulation by way of a passing FSES, they shall document this plan on the Plan of Correction (POC). Refer to the State Operations Manual, Ch 7, Survey and Enforcement Process.¹

Keep in mind for the first POC opportunity:

- The (X5) Credible Allegation Date (CAD) cannot exceed Day 60 from survey exit.
- The (X5) CAD cannot exceed Day 90 from the start of any open survey enforcement cycle (allotted timeframe).

Achieving Compliance by Equivalency

A passing FSES is required to 'compliance' the citation as a component or part of the POC implementation.

If the FSES fails in any zone, then the FSES is not passing and will not be an accepted means towards compliance.

Achieving Compliance by Equivalency

After POC approval and at the time of survey revisit, the following documents shall be provided to the Department for review:

1. Justification letter (cover letter).

- The cover letter shall include, at minimum, the building's construction type, occupancy classifications, number of stories, and any other special conditions of the building's floors, zones or units.
- The cover letter must explain the existing conditions to justify the scoring for the FSES worksheets; describe the deficient condition and where it exists in the building. **A cover letter that only restates the FSES scores shall be deemed insufficient.**

Achieving Compliance by Equivalency

2. FSES worksheets.

- If there are other citations from the same survey, and they have been corrected prior to the date of the FSES report, the corrective work shall be explained within the POC and/or FSES document package.

3. LSC drawings/floor plans.

- LSC plans for all levels with each smoke compartment zone shall be provided and labeled according to the zones on the FSES worksheets and shall include life safety design features.

Achieving Compliance by Equivalency

A passing FSES is required to 'compliance' the citation as part of the POC implementation.

Per CMS State Operations Manual *Appendix I, Survey Procedures for Life Safety Code Surveys*, FSES's submitted by the facility as part of the survey POC must be reviewed by the Department. Those FSES's that receive a passing score and a Department recommendation must be forwarded by the Department to the CMS Regional Office for review and final approval. The CMS Regional Office will notify the Department and the facility upon its final approval of the submitted FSES.¹

Achieving Compliance by Equivalency

Considerations for the provider to ask themselves when determining their path toward compliance:

Can equivalency be achieved by Credible Allegation Date (CAD)?

Or, in other words:

Will the FSES – if conducted by CAD – result in a ‘passing score’?

The facility does not need to complete an FSES if they know the building will fail the FSES. If you know the FSES will not pass by CAD, then the option to attempt equivalency by FSES is not an acceptable POC.

Achieving Compliance by Equivalency

Recap:

As CMS describes in their FSES training: There are three ways that a CMS-certified facility can demonstrate an acceptable level of compliance with LSC requirements:³

1. Meeting prescriptive requirements of the LSC;
2. Showing compliance by providing an acceptable performance-based life safety design; or
3. If a facility is unable to demonstrate compliance with the prescriptive requirements of the LSC, a determination of equivalency with the LSC may be made using an FSES evaluation.

Achieving Compliance by Equivalency

Waivers are an option for facilities that are not in compliance with the LSC, but they do not demonstrate compliance. Instead, waivers allow the facility time to continue operating while pursuing one of the three methods.³

A facility should opt for a waiver request if they cannot demonstrate an acceptable level of compliance with LSC requirements within 90 days of the allotted timeframe due to unavoidable extenuating circumstances.

What is a Waiver?

A waiver is permitted by regulation and allows for temporary non-compliance with specific provisions of the LSC for a specified period of time. Waivers may be time-limited or continuing.³

Time-limited waivers may be granted for a short duration when a facility requires more time to correct a deficiency than permitted by normal enforcement timelines—for example, if additional time is needed to complete a construction project that is expected to bring the facility into compliance.³

- Waivers can be applied to specific F tags and K tags.

Continuing waivers are granted for extended periods of time when a deficiency is considered impracticable to correct—for example, if compliance with width requirements in a specific facility corridor is impeded by a structural column.³

- Continuing waivers can be applied to specific State I tags.

What is a Waiver?

CMS also issues Categorical waivers. Categorical waivers are submitted by the provider at the time of survey and not after issuance of the SOD.

Follow the CMS SOM and applicable guidance including but not limited to CMS Survey & Certification (S&C) and CMS Quality, Safety & Oversight (QSO) memorandum regarding Categorical waivers.

Categorical waivers are not discussed within this presentation.

What is a Waiver?

With FSES reports, building construction type and waivers, please note:

CMS memo **revised 10-26-2022** and titled, '*S&C 17-15, Use of the Fire Safety Evaluation System (FSES), National Fire Protection Association (NFPA) 101A, Guide on Alternative Approaches to Life Safety, 2013 Edition by Health Care Occupancies and Board and Care Occupancies.*'⁶

6. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions?items_per_page=10&combine=17-15&order=dlf_3_posting_date&sort=desc

Equivalency versus Waiver

As CMS describes in their FSES training:³

Equivalency	Waiver
Permitted by Life Safety Code (LSC).	Permitted by Regulation
Demonstrates fire protection considered equal to that provided by LSC requirements	Allows for temporary non-compliance with LSC.

Example of Not Meeting Equivalency

Scenario 1:

Provider 'A' operates a Skilled Nursing Facility (SNF) that participates in the Medicare/Medicaid program and has an active Department-issued Operating Certificate. Their campus consists of two SNF buildings: Building #1 (2 stories with basement) and Building #2 (4 stories without basement).

During a Standard LSC survey, the surveyor determines both buildings will be surveyed under Chapter 19 of the 2012 edition of *NFPA 101 (the Code)*, Existing Health Care Occupancies.

Based on observation, interview, and/or record review, the surveyor determines Building #2 does not meet minimum building construction type in accordance with *the Code*. This deficiency is cited as K161 on the SOD.

Example of Not Meeting Equivalency

Scenario 1 (cont.):

Provider 'A' reviews the SOD. The K161 citation for Building #2 indicates the entire building lacks the required minimum fire-resistance rating for the floor-ceiling assembly and was deemed to be of Type II (000). The citation indicates that for a building that is 4 stories tall, minimum building construction type per NFPA requires Type II (222).

Provider 'A' reviews the SOD letter.

- Under Bullet 2 of 'what the POC must contain' heading, the facility is instructed to describe "how you will identify other residents having the potential to be affected by the same deficient practice and what corrective action will be taken."
- In preparing the POC narrative, Provider 'A' determines the K161 deficiency applies to all floor-ceiling assemblies throughout the building on floors 1 through 4.

Example of Not Meeting Equivalency

Scenario 1 (cont.):

Provider 'A' considers their options:

- ☐ Option 1: Prescriptive Code Compliance
- ☐ Option 2: Equivalency
- ☐ Option 3: Waiver

Example of Not Meeting Equivalency

Scenario 1 (cont.):

Provider 'A' reviews past survey documentation.

- They had not previously achieved compliance from an equivalency. In other words, the provider always met prescriptive code requirements in correcting deficiencies and had never completed/submitted an FSES report to the NYSDOH for Building #2 as result of an SOD.
- ❑ Option 1: The provider determines they cannot meet prescriptive code requirements of K161 without substantial time and substantial work, not within the allotted timeframe.

Example of Not Meeting Equivalency

Scenario 1 (cont.):

After reviewing 2013 edition of NFPA 101A, *Guide on Alternative Approaches to Life Safety*, Provider 'A' determines an FSES, even with the highest scoring values for all categories, will still fail because buildings equal to or greater than 3 stories will not pass a FSES using the 2013 FSES values (worksheet 4.7.8B) if there is a construction type deficiency.

Provider 'A' then reads CMS S&C 17-15 memo ⁶ (revised 10-24-2022) and determines they must use the 2013 FSES minimum scoring values.

- ☐ Option 2: The provider determines they cannot meet equivalency for K161 within the allotted timeframe.

Example of Not Meeting Equivalency

Scenario 1 (cont.):

Provider 'A' knows that Building #2 will fail an FSES based on current conditions. They also know that if an FSES was conducted by CAD, the FSES would fail because:

- K161 is cited (building construction type), and
- The building is 4 stories, and
- Would use the 2013 FSES minimum scoring values per the CMS 17-15 memo.

Example of Not Meeting Equivalency

Scenario 1 (cont.):

Having exhausted Options 1 and 2, 'Provider A' moves to Option 3, a waiver request.

- Note: No FSES was conducted in order to make this determination. This was completed internally, by the provider, and prior to POC submission as an assessment of what options are feasible.
- This assessment will inform the provider on viable paths toward compliance.

Waivers of Federal Code

The Secretary of the Department of Health and Human Services (DHHS) has delegated to CMS the authority to grant waivers of Code provisions for facilities participating in Medicare and Medicaid, with the exception of Intermediate Care Facilities for Individuals with Intellectual Disabilities, or ICFs/IID.¹

The Code permits the Authority Having Jurisdiction (AHJ) to determine the adequacy of protection provided for life safety from fire in accordance with the provisions of the Code. There can be many AHJs, however CMS is the AHJ for Medicare and Medicaid certification.¹

Approval of all Federal Code waivers and FSES requests for certified health care facilities must be determined by CMS.¹

The State Survey Agency, the NYS Department of Health, may recommend Code waivers, but only the CMS Regional Office can grant waivers. Therefore, any Code waiver request received by a facility that the Department recommends must be forwarded to CMS for adjudication.¹

Federal Temporary Waivers

Review CMS SOM including but not limited to § 7410.6.1

“A temporary waiver for a defined time period may be considered for a finding for which corrective action will take more than 90 days to complete. If a waiver is granted during that time, sanctions will not be imposed under the long-term care enforcement regulations. Examples of the type of corrective action that could warrant a temporary waiver could include installation of a sprinkler system or a smoke barrier. Examples of deficiencies that could warrant such waivers include the obstruction of exiting, penetrations of smoke barriers, and increased travel distances to exits due to new construction or remodeling of a wing of a facility. In these cases, the waiver would be for a reasonable period of time for construction activities, including planning and design.”¹

Federal Temporary Waivers

Review CMS SOM including but not limited to § 7410.6.1 (cont.)

“The waiver documentation submitted by the facility for approval would include a timetable with milestone dates of major activities to correct the deficiency that the surveyor could monitor on any subsequent follow-up visits. Extensions and modifications of this timetable are not envisioned except under extreme circumstances. Failure of the facility to follow the timetable and the milestones established in the approved temporary waiver would subject the facility to the remedies prescribed in the enforcement regulations. If the construction activities are completed within the agreed upon timetable and the deficiency is corrected, the existence of the waiver is no longer cited on the Form CMS-2567.”¹

Federal Temporary Waivers

Review CMS SOM including but not limited to § 7410.6.1 (cont.)

“When the temporary waiver of life safety code requirements is in effect, the facility should have increased fire safety awareness. This increased fire safety awareness may include the establishment of interim safety measures such as a fire watch during construction, an increased number of fire drills and training of staff at the facility, or other measures that would provide an increased measure of fire protection.”¹

Federal Continuing Waivers

Review CMS SOM including but not limited to § 7410.6.2

“Continuing waivers of a specific life safety code requirement are granted when the noncompliance cannot be corrected without an unreasonable financial hardship on the facility and it does not pose a threat to residents’ health and safety. The State cites the deficiency on each annual survey although they do not expect it to be corrected by the facility due to the existence of the waiver. Examples of this type of finding may include improper corridor width either before or after remodeling, a dead-end corridor longer than the specified life safety code length, a specific construction type not met, a noncompliant interior finish type, excessive exit travel distance, or waiting areas open to the corridor in a non-sprinklered facility.”¹

Federal Continuing Waivers

Review CMS SOM including but not limited to § 7410.6.2 (cont.)

“CMS grants waivers after an evaluation of the specific life safety code deficiency cited and its impact on the life safety of the facility. A waiver of a life safety code requirement that cannot be corrected and which is likely to be cited on each future life safety code survey may be granted for more than 1 year or survey interval. For example, CMS could grant a waiver for a 3-year period after which the State reviews it during the life safety code survey; if the waiver is still appropriate, it can be extended for another 3-year period. The survey agency cites the deficiency on the annual survey and on the Form CMS-2567 but reviews the waiver only after the expiration of the 3-year period. The plan of correction, submitted by the facility for that deficiency, would cite the existence of a waiver.”¹

State Code Waivers

The facility may submit a request for a continuing waiver.

- **State waiver resulting from a survey of licensed facilities.**

Waivers of Exception may be requested for Facility Guidelines Institute (FGI), the Americans with Disabilities Act (ADA), or provisions under state regulation cited during surveys. These waivers may be granted due to demonstrated hardship where the deficiency is not detrimental to the health and safety of the occupants.²

- **State continuing waivers stay with the building and do not expire with a Change of Ownership (CHOW).**

Facilities should ensure waiver documentation is kept onsite for review by staff and AHJ.

Recap: Prescriptive Code, Equivalency, Waivers

To recap, we discussed how providers can choose to employ alternate means to meet prescriptive code requirements (equivalency), but are required to do so within the allotted timeframe.

We also discussed how providers, if not able to achieve compliance within the allotted timeframe, may elect to request waivers of time (temporary, time-limited) or continuing (hardship).

- Federal Regulation: Approved waivers allow for temporary noncompliance with Federal code requirements.³
- State Regulation: Approved continuing waivers allow for continued noncompliance with State code requirements.⁵

2. Submission Guidelines

Submission Guidelines

There are three overarching steps to request a waiver:

1. The facility shall consult the “Waiver and Equivalency Submission Guidelines”⁵ and CMS guidance.
2. The facility shall document such waiver requests under the appropriate tag in their Plan of Correction (POC). The POC shall be the official record of the waiver request.
3. Waiver supporting documentation shall be submitted to the Department at LTCLSCwaivers@health.ny.gov.

5. https://www.health.ny.gov/facilities/cons/docs/waiver_equivalency_submission_guidelines.pdf

Step 1, Read Submission Guidelines

The Department “Waiver and Equivalency Submission Guidelines” document describes the kinds of waivers a provider may and may not request for a specific deficiency, and provides guidance on what supporting documents are required to consider the waiver as potentially approvable.

Guideline in Broken into Sections

Section A

State Waiver

FGI, ADA, State Regulations

Section B

Federal Waiver

Life Safety Code, and Special Waivers Applicable to
Skilled Nursing Facilities and Nursing Facilities

Section C

Federal Equivalency

Life Safety Code

Section D

Federal Post Waiver Approval

Step 2, Determine Plan for Plan of Correction

After reviewing possible options, the provider should determine their path toward compliance and document on the POC. Some questions to consider include:

1. Can the facility meet equivalency in the allotted timeframe?
If Yes, then Equivalency may be feasible within the allotted timeframe, so no waiver.
2. Can the facility **meet prescriptive code** requirements if **given extra TIME** to do so?
If Yes, then consider a Temporary, Time-Limited Waiver request to meet CODE.
3. Can the facility **meet equivalency** if **given extra TIME** to do so?
If Yes, then consider a Temporary, Time-Limited Waiver request to meet EQUIVALENCY.
4. Does the facility's plan negatively impact health and safety of residents/staff?
5. Will the facility's plan result in not meeting prescriptive code of another requirement?

Step 2, Determine Plan for Plan of Correction

Waiver requests documented on the POC shall include all necessary information including but not limited to:

1. Detailed information to explain why the facility cannot achieve compliance.
 - a. For temporary waivers: within the allotted timeframe.
 - b. For continuing waivers: why compliance is not achievable.
2. The type of waiver requested.
3. The requested expiration/end date for the waiver.
4. Interim life safety measures that are in place while the deficiency exists.
5. Applicable elements as required by CMS.

Step 2, Determine Plan for Plan of Correction

5. Applicable elements as required by CMS.

- a. CMS State Operations Manual, Chapter 2, The Certification Process, Section 2480, *LSC Waivers*.¹
- b. CMS State Operations Manual, Chapter 2, The Certification Process, Section 2480C, *Elements Considered in Determination of Unreasonable Hardship*.¹
- c. CMS memo **revised 10-26-2022** and titled, 'S&C 17-15, *Use of the Fire Safety Evaluation System (FSES), National Fire Protection Association (NFPA) 101A, Guide on Alternative Approaches to Life Safety, 2013 Edition by Health Care Occupancies and Board and Care Occupancies*.'⁶

6. https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions?items_per_page=10&combine=17-15&order=dlf_3_posting_date&sort=desc

Step 2, Determine Plan for Plan of Correction

Additionally for temporary, time-limited waivers, the POC shall include:

6. Statement that the facility will determine applicability of a Certificate of Need (CON) application or Construction Notice as required by Public Health Law Article 28.
7. Narrative that explains if, after work, the result will be to meet prescriptive code or equivalency.
 - a. If equivalency,
 - i. The facility shall document on the POC that upon work completion, the facility will meet equivalency with a passing FSES in accordance with the 2013 edition of NFPA 101A - *Guide on Alternative Approaches to Life Safety*. The POC shall be the official record of the use of a passing FSES.

Step 2, Determine Plan for Plan of Correction

Additionally for temporary, time-limited waivers, the POC shall include (cont.):

8. The projected timeframe for corrective action with milestone dates (MM-DD-YY) organized by floor or zone.
9. Statement that the facility will submit progress reports to LTCLSCwaivers@health.ny.gov at least quarterly from the date of waiver approval.

Step 3, Email Supporting Documents

After determining the path towards compliance and documenting this plan on the POC, the facility shall submit appropriate supporting documentation to LTCLSCwaivers@health.ny.gov.

This mailbox is staffed by Long Term Care Survey and Operations team members at each Department Regional Office.

There is no waiver request form for Federal code requirements. The POC shall be the official record of the waiver request.

Step 3, Email Supporting Documents

Upon receipt of the waiver request, the provider will be notified of their assigned DOH waiver number to be included in the email subject line for all correspondence. The Department will contact the applicant if additional information is needed.

Please note that an acceptable Plan of Correction in the Health Commerce System does not constitute an approved waiver.

Submission Guidelines Recap

To recap, we discussed the waiver process as required by State and Federal regulations and guidance, with three overarching steps to request a waiver.

We also discussed that, dependent upon the provider's plan toward compliance, there are certain required elements needed within a POC in order for the POC to be deemed 'potentially approvable.' Providers should refer to CMS SOM and guidance documents for these required elements.

3. Enforcement

Enforcement with Waivers in Progress

The Enforcement Cycle begins with any survey that finds noncompliance (Recertification, Standard, Abbreviated, Complaint, Focused Infection Control Survey, LSC, temporary waiver revisit, Health, etc.):

CMS State Operations Manual, Chapter 7, 7400 - *Enforcement Remedies for Skilled Nursing Facilities (SNFs), Nursing Facilities (NFs) and Dually Participating Facilities (SNFs/NFs)*

Sections 1819(h) and 1919(h) of the Act, as well as 42 CFR §§ 488.404, 488.406, and 488.408, provide that CMS or the State may impose one or more remedies in addition to, or instead of, termination of the provider agreement when the State or CMS finds that a facility is out of compliance with federal requirements. Enforcement protocols/procedures are based on the premise that all requirements must be met and take on greater or lesser significance depending on the specific circumstances and resident outcomes in each facility.¹

Enforcement with Waivers in Progress

State Operations Manual, Chapter 7, 7410.1 - *Application of the Enforcement Regulations to Life Safety Code Surveys Conducted in Skilled Nursing Facilities and Nursing Facilities*

Skilled nursing facilities and nursing facilities must meet the requirements at 42 CFR Part 483, Subpart B, in order to receive payment under Medicare or Medicaid. To certify a skilled nursing facility or nursing facility, complete at least a standard health survey and a life safety code survey. Nursing home enforcement regulations at 42 CFR Part 488, Subpart F, are also applicable to life safety code surveys.¹

Enforcement with Waivers in Progress

The Enforcement Cycle ends when substantial compliance is achieved in that enforcement case:

State Operations Manual, Chapter 7, 7317.3 - *Noncompliance Cycles*

A noncompliance cycle begins with a recertification, complaint or temporary waiver revisit survey that finds noncompliance and ends when substantial compliance is achieved or the facility is terminated (or voluntarily terminates) from the Medicare or Medicaid program. (See also §7001.) The noncompliance cycle cannot exceed 6 months. Once a remedy is imposed, it continues until the facility is in substantial compliance (and in some cases, until it can demonstrate that it can remain in substantial compliance), or is terminated from the programs.¹

Enforcement with Waivers in Progress

The Enforcement Cycle is documented within an enforcement case.

The case continues so long as citations are still out of compliance in a survey.

A citation with a POC stating that there is a waiver request will require a waiver approval. If the citation is Federal, only CMS can approve or deny a waiver request. Until CMS issues a waiver determination, the facility remains out of compliance .

The case ends when all citations are complianced or are deemed by the AHJ as waived or meeting equivalency.

Reminders

Facilities are reminded that all waiver requests must be submitted timely to allow for sufficient review time. The Department cannot guarantee that CMS will approve a waiver request before the Mandatory Denial of Payments for New Admissions (DOPNA) date.

CMS does not grant permanent waivers or waiver extensions of Federal code.

CMS does not grant time-limited waivers to complete/procure an FSES report.

Recap

To recap, we discussed non-compliance cycles and enforcement cycles when a provider elects to request a waiver for a specific deficiency.

Facilities are considered out of compliance until:

- The deficiency is corrected, or
- CMS approves the Federal waiver request, or
- CMS approves a passing FSES, or
- The Department approves a State waiver request.

4. Waiver Determinations

Request for Additional Information

- All correspondence regarding the waiver request shall be conducted via email to and from LTCLSCwaivers@health.ny.gov. The Department will consult as necessary.
- There should be no discrepancies between the Plan of Correction and supporting documentation. If a facility makes changes during the waiver review process, the changes need to be communicated to LTCLSCwaivers@health.ny.gov and the facility must ensure that the information across all documents align as one cohesive waiver package.
- Additional supporting documentation may be requested at the discretion of the Department and/or CMS for sufficient information to render a waiver recommendation and/or determination.

Request for Additional Information

For Federal waiver requests:

- When the Department has received and reviewed all necessary documentation, and has deemed the request sufficient to render a determination, the Department will submit the waiver request to CMS and will recommend approval.
- Please note that although the Department issues recommendations, CMS is the approval authority for Federal waivers. Only CMS can grant waivers of Federal code requirements.
- CMS will notify the Department of waiver determinations. Facilities will be notified of CMS's decision through LTCLSCwaivers@health.ny.gov.
- If documentation is insufficient to render a determination, the facility shall submit additional information to the satisfaction of the Department and CMS.

If a Waiver is Denied

- The Department will inform the facility of the decision via LTCLSCwaivers@health.ny.gov.
- Facility will remain out of compliance.
- Facility will develop a new plan of action for how to come into compliance. If waiver is needed, waiver process begins again.
 - The facility supplies a new request via the electronic Plan of Correction and supplies supporting documents.

For Federal waiver requests:

- CMS issues denied waiver determination letters to the facility. If the facility does not receive a copy, they may request one from the Department via LTCLSCwaivers@health.ny.gov.

If a Waiver is Approved

- The Department will inform the facility of the decision.
- The Plan of Correction is deemed approved.
- The Department will complete a final desk review, enter completion dates for remaining tags for that initial survey type, and will enter waiver information for the applicable tag.
- If all citations in the enforcement case are back in compliance, then the substantial compliance date is determined & facility will receive a 'back in compliance' letter.
- For Federal waivers, CMS issues approved waiver determination letters. If the facility does not receive a copy, they may request a copy from LTCLSCwaivers@health.ny.gov.
 - The letter will contain a 'last day in effect' (expiration date).

Recap

To recap, we discussed the Department's and CMS' expectations for providers that request a waiver during the waiver review and determination process.

5. Facility Obligations After Approval

After a Waiver is Approved

For temporary, time-limited waivers:

As a condition of waiver approval, the provider is to supply progress reports on the project and corrective action to DOH at least quarterly to show that continual progress is being made to allow for corrective action by the expiration of the time-limited waiver.

Please send updates to LTCLSCwaivers@health.ny.gov and ensure the facility name and Department-assigned waiver number is included in the email subject line.

Takeaways on Waiver Approval

- Waivers are for a specified time and have expiration dates.
- A waiver approval is utilized to waive a specific code requirement.
- Facilities that do not meet prescriptive code are cited.
- If the facility has an active waiver (not expired), that would be documented on the facility's Plan of Correction.
- Subsequent to initial survey of a brand new facility, there is no opportunity to request a waiver outside of an enforcement case.

Recap

To recap, we discussed:

- How a waiver is permitted by regulation and allows for temporary noncompliance with specific provisions of code for a specified period of time, and
- The Department's and CMS' expectations for providers with approved waivers, and
- Facilities that do not meet prescriptive code requirements are cited.

Facilities are reminded that all waiver requests must be submitted timely to allow for sufficient review time. **The Department cannot guarantee that CMS will approve a waiver request or a passing FSES before the Mandatory DOPNA date.**

Summary

Summary

We discussed:

- 1.The application of waivers to waive State and Federal code requirements.
- 2.The waiver process as required by State and Federal regulations and guidance.
3. The Departments' and CMS' expectations for providers that request a waiver.

References

References

1. CMS State Operations Manual (SOM). Available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS1201984>
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Waiver & Equivalency Submission Guidelines

Questions may be referred to the Department of Health Regional Office.

Thank you!