HOSPITAL WAIVERS AND VARIANCES

Hospitals may encounter periods when delivery of care is strained or even impossible under current regulatory and licensing requirements. Depending on the situation, hospitals may be able to request regulatory and licensing flexibility allowing them to continue to meet the demands for care in the community. The Centers for Medicare & Medicaid Services is authorized to issue or approve 1135 waiver requests under certain conditions. In addition, hospitals can request a variance from the Department of Health and Senior Services when a variance of a state hospital licensing regulation, under the department's purview is needed. Some CMS waiver requests will need to be accompanied by a state variance request when the state has a different requirement than that of the Conditions of Participations which are incorporated by reference under Section 197.005, RSMo.

CMS SECTION 1135 WAIVER REQUESTS

Prerequisites for a Section 1135 Waiver

There are four requirements that must be met before a hospital or other health care facility can obtain a waiver under Section 1135 of the Social Security Act.

1. The President has declared an emergency or disaster under the Stafford Act or the National Emergencies Act.
2. The Secretary of U.S. Department of Health and Human Services has declared a Public Health Emergency under Section 319 of the Public Health Service Act.
3. The Secretary of HHS has invoked authority under Section 1135 of the Social Security Act and authorized the Centers for Medicare & Medicaid Services to waive sanctions for certain regulations that arise as a result of the circumstances of the emergency.
4. The hospital in the affected area has documented implementation of its hospital disaster protocol.

Waivers Available Under Section 1135

When the President declares a major disaster or an emergency and the HHS Secretary declares a public health emergency, the Secretary is authorized to take certain actions in addition to his regular authorities. The Secretary has the authority to waive or modify certain federal laws and regulations. Examples of 1135 waivers or modifications include the following.

- conditions of participation or certification under Medicare, Medicaid and State Children's Health Insurance Program
- preapproval requirements under Medicare, Medicaid and State Children's Health Insurance Program
- State licenses for physicians and other health care professionals (this waiver is for purposes of Medicare, Medicaid and SCHIP reimbursement only — the state determines whether a nonfederal provider is authorized to provide services in the state without state licensure)

- Emergency Medical Treatment and Labor Act sanctions for:
    - redirection of an individual to another location to receive a medical screening examination
        - pursuant to a state emergency preparedness plan, in the case of a public health emergency that involves a pandemic infectious disease, pursuant to a state pandemic preparedness plan
        - transfer of an individual who has not been stabilized if the transfer arises out of emergency circumstances. A waiver of EMTALA requirements only is effective if actions under the waiver do not discriminate based on a patient's source of payment or ability to pay.
- Stark self-referral sanctions
- Performance deadlines and timetables may be adjusted (but not waived).
- Limitations on payments for health care items and services to permit Medicare+Choice enrollees to use out-of-network providers in an emergency

In addition, the Secretary may waive Health Insurance Portability and Accountability Act sanctions and penalties relating to the following.

- Obtaining a patient's consent to speak with family members or friends
- Honoring a patient's request to opt out of the facility directory
- Distributing a note of privacy practices
- Honoring the patient's right to request privacy restrictions or confidential communications

The waiver of HIPPA requirements only is effective if actions under the waiver do not discriminate based on a patient's source of payment or ability to pay.

In addition to the 1135 waiver authority, Section 1812(f) of the Social Security Act (the Act) authorizes the Secretary to provide for skilled nursing facility coverage in the absence of a qualifying hospital stay, if this action does not increase overall program payments and does not alter the SNF benefit's "acute care nature" (that is, its orientation toward relatively short-term and intensive care).

Duration of a Section 1135 Waiver

These waivers under Section 1135 of the Social Security Act typically end with the termination of the emergency period, or 60 days from the date the waiver or modification is first published unless the Secretary of HHS extends the waiver by notice for additional periods of up to 60 days. Waivers for EMTALA (for emergencies that do not involve a pandemic disease) and HIPAA requirements are limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. Waiver of EMTALA requirements for emergencies that involve a pandemic disease last until the termination of the pandemic-related emergency. The waiver for licensure applies only to federal requirements and does not automatically apply to state requirements for licensure or conditions of participation.

A waiver or modification of requirements may, at the Secretary's discretion, be made retroactive to the beginning of the emergency period or any subsequent date in such a period specified by the Secretary.

Procedure for Obtaining a Section 1135 Waiver

Blanket Waivers

According to CMS, when CMS issues a national "blanket waiver" there is nothing else the state or health care provider must do to be considered a part of the waiver and for the waiver to be considered in-effect.

Individual CMS Waiver Requests

Once a Section 1135 Waiver authority is authorized, states or individual health care providers can submit requests to operate under that authority or for other relief that may be possible outside the authority to:

- the web portal to access 1135 waiver requests and inquiries are located at: CMS PHE Emergency Web Portal
- Questions regarding 1135 that are not addressed at the above website can be sent to the following 1135Waiver@cms.hhs.gov

DHSS VARIANCE REQUEST

There are no prerequisites for requesting a variance from DHSS. In the event there is a state Declaration of Emergency, the DHSS director may issue variances (sometimes called waivers) on a blanket basis like the CMS 1135 process. Otherwise, even when there is no state declaration, hospitals licensed under 19 CSR 30-20.015 may request a variance from the requirements of 19 CSR 30-20. The requests must be in writing to the Department of Health and Senior Services, Bureau of Hospital Licensure and Standards. DHSS' determinations in response to variance requests must be in writing and both requests and determinations will be made a part of the DHSS' permanent records for the facility.

DHSS' written determination must identify a variance expiration date, if approved. The facility may reapply for a variance up to ninety (90) days prior to the expiration of a department-approved variance. Any facility granted a variance by the department must inform DHSS in writing if the conditions warranting the variance change. This written notification to DHSS must be made within thirty (30) days of the change affecting the variance. DHSS may revoke the granted variance if the changes in conditions detrimentally impact the health, safety and the welfare of the patient, staff or public, as determined by DHSS. All previously approved variances must be submitted at the time of annual licensure renewal.

Attn:
Richard Grindstaff, Bureau Chief
Hospital Licensure and Standards
Richard.grindstaff@heath.mo.gov or HospitalLicensure@health.mo.gov
912 Wildwood
P.O. Box 570
Jefferson City, MO 65102
Phone: 573-751-6400 Fax: 573-751-6010

MEDICAID VARIANCE REQUESTS

Hospitals should contact MHA staff for questions about variances to, or waivers of, Medicaid operating policies. MHA staff will work with MO HealthNet Division to determine if and how temporary changes can be made to accommodate emergency conditions. MHA will monitor changes granted by licensure boards, Medicare and other authorities and, when appropriate request that MHD accordingly modify its policies.

LICENSURE BOARD REQUESTS

Many of the boards within Professional Registration and Licensing have the authority to grant certain licensing exceptions under certain conditions. Within some boards, the authority to waive certain requirements only may exist if there is a declared emergency while other requirements may have exceptions that can be granted by the board itself or through the emergency rulemaking process. MHA will work with hospitals to identify the best route to make a request depending on the need and situation.

WHAT TO INCLUDE IN A VARIANCE OR WAIVER REQUEST

The provider or hospital requesting the Section 1135 Waiver or state hospital licensing variance, should provide at a minimum the following information.

- Provider Name/Type
- Full Address (including county, city/town, state)
- CCN (Medicare provider number)
- Contact person and his or her contact information for follow-up questions should CMS or the department need additional clarification
- Summary of why the waiver or variance is needed. Specific reason why compliance with the rule would impose an undue hardship on the operator, including an estimate of any additional costs which might be involved. The following example is one that may require a CMS waiver in addition to a hospital licensing variance:
    - Waiver example: Critical Access Hospital is the sole community provider without reasonable transfer options during the specified emergent event (e.g., flooding, tornado, fires, or flu outbreak). CAH needs a waiver of 42 CFR 485.608 to exceed its twenty-five bed limit by X number of beds for Y days/weeks — be specific.
    - Variance example: Critical Access Hospital is sole community provider without reasonable transfer options during the specified emergent event (e.g., flooding, tornado, fires or flu outbreak). CAH needs a waiver of 19 CSR 30-20.015 to exceed its twenty-five bed limit by X number of beds for Y days/weeks — be specific.
- An explanation of the extenuating factors which may be relevant including a complete description of the individual characteristics of the facility or patients or any other factors which would fulfill the intent of the rule in question to safeguard the health, safety and the welfare of the patient, staff or public if the waiver or variance from the requirement is granted; and length of time the variance is being requested. Waivers have specified periods of time for which they are in effect — see above.
- Consideration — type of relief you are seeking or regulatory requirements or regulatory reference that the requestor is seeking to be waived — see example above. This should

include the specific Condition of Participation or state regulation reference including the text being requested to be waived or varied.

- There is no specific form or format that is required to submit the information, but it is helpful to clearly state the scope of the issue and the impact.