

Hospital Alternative Care Sites during H1N1 Public Health Emergency

With the ongoing outbreaks of the 2009 novel H1N1flu this fall, there are some hospitals that may experience a surge in the number of individuals presenting to emergency departments (ED) for evaluation and treatment for H1N1 illness. In some cases, hospitals may find it necessary to establish alternative care sites to expand the ability of the facility to care for patients. Below is guidance related to payment, conditions of participation and standards of care related to alternative care sites. A separate fact sheet related to EMTALA can be found at:

http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf

While this document discusses section 1135 waiver authorities, *it is for informational purposes only* and should not be construed as a commitment to provide any waiver.

I. Payment for care at alternative care sites

- A. Will CMS recognize care provided at alternate care sites and provide appropriate payment?

Medicaid: Under the Medicaid program, States may request authority from CMS to provide medical assistance to patients and residents who are treated in alternative care sites to the extent required to protect beneficiary health and safety. All providers will be expected to provide safe and quality care to patients and residents in the alternative setting, and to transfer to an appropriate setting as quickly as possible. CMS may grant such requests using section 1135 waivers if the Secretary determines they are appropriate. Because Medicaid hospitals must comply with Medicare hospital Conditions of Participation (CoPs), the practical effect probably would be that the same waivers that would make services payable under Medicare would also permit them to be paid under Medicaid state plans.

Medicare: CMS is constrained by the detailed requirements of Title XVIII of the Social Security Act (the Act) and its implementing regulations and is limited in the flexibilities it can invoke in an emergency or disaster. Some Medicare flexibilities become available only when the Secretary has authorized them through the use of waiver authority under section 1135 of the Act, which itself may be invoked only if the President has declared an emergency or disaster under the Stafford Act or National Emergencies Act and the Secretary has declared a public health emergency under Section 319 of the Public Health Service Act. Nevertheless, CMS has developed a broad array of flexibilities that can be invoked in an emergency or disaster. These flexibilities, some of which are available under normal business rules and some of which require a section 1135 waiver, are intended to ease administrative burden on the industry and promote access to care by beneficiaries. These flexibilities are discussed in this fact sheet.

- B. What are the definitions of emergency department to meet the threshold for payment and how broadly is it interpreted to accommodate alternative settings (primary care clinics, triage tents, etc.)?

The EMTALA regulations at 42 CFR 489.24 (b) contain a definition of a “dedicated emergency department,” which is as follows: “*Dedicated emergency department* means any department or facility of the hospital, regardless of whether it is located on or off the main hospital campus, that meets at least one of the following requirements:

- (1) It is licensed by the State in which it is located under applicable State law as an emergency room or emergency department;
- (2) It is held out to the public (by name, posted signs, advertising, or other means) as a place that provides care for emergency medical conditions on an urgent basis without requiring a previously scheduled appointment; or
- (3) During the calendar year immediately preceding the calendar year in which a determination under this section is being made, based on a representative sample of patient visits that occurred during that calendar year, it provides at least one-third of all of its outpatient visits for the treatment of emergency medical conditions on an urgent basis without requiring a previously scheduled appointment.”

Any alternative care site that meets the requirements to be considered part of the hospital and which also meets the EMTALA definition above would be considered a hospital emergency department.

- C. Can patients be diverted for emergency triage or minor care and discharge at an alternative care sites (tent, flu screening kiosk, etc.)?

CMS has prepared a Fact Sheet that explains what hospitals can do while continuing to comply with EMTALA requirements. The Fact sheet can be found at the following website:

http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf

- D. Can care at an alternative care site be reimbursed as an emergency department (ED) visit?

Medicaid: CMS will provide FMAP to States for services provided at approved alternative care facilities to Medicaid eligible individuals for services that are coverable under the Medicaid State plan. States will make provider payments to alternative care facilities based upon State reimbursement methodologies for such facilities.

Medicare: ED visits may only be provided by a hospital or CAH. Medicare payment for services at an alternative care site that is part of a Medicare-participating hospital or CAH may be permissible. Whether an “alternative care site” qualifies as an ED and provides Medicare-covered services will depend to a great extent on the facts and circumstances of each case.

Medicare CoPs apply to alternative care sites that are part of hospitals or CAHs unless such CoPs are waived under section 1135 of the Act. Emergency department visits (CPT codes 99281 to 99285 or HCPCS codes G0380 to G0384, as appropriate) can only be billed for services provided in an organized hospital-based facility for the provision of unscheduled episodic services to patients who present for immediate medical attention. If these alternative care sites are not organized hospital-based facilities for the provision of unscheduled episodic care, the emergency department visit codes cannot be used to bill for visit services. However, to the extent an alternative hospital-based site of care meets Medicare requirements, the hospital may bill Medicare for clinic visit services (CPT codes 99201 to 99205 or 99211 through 99215, as appropriate) that are furnished. Even if a section 1135 waiver is in place with respect to the hospitals’ or CAH’s compliance with CoPs, an emergency department visit could only be billed if the alternative care site has been determined to be an organized hospital-based alternate care site.

- E. Will CMS accept claims for services that are provided by healthcare professionals who, in normal circumstances, would not be permitted by Medicare to provide services to beneficiaries; such as registered nurses (RNs) providing care typically provided by physicians or residents/medical students providing services without the required level of physician supervision?

With respect to original fee-for-service Medicare (FFS), there is no authority under Medicare Part B that authorizes Medicare to depart from the statutory provisions that specify to whom Medicare payment is made. Medicare payment cannot be made under the physician fee schedule (PFS) directly to an RN or any other individual without a separately enumerated benefit under Medicare law. The only way that Medicare can pay for the services of these individuals under Part B is indirectly under the “incident to” provision. The “incident to” provision for physicians’ services requires, among other things, that PFS payment is made to the employer of those who furnish services incident to a physician’s (or to certain types of non-physician practitioner’s) professional service and that the services be furnished under direct supervision by a physician (or certain types of nonphysician practitioners). Hence, those who provide “incident to” services must be employed, leased, or contracted with the physician or nonphysician practitioner, or the entity that bills for their services. Therapeutic services provided by hospital staff to hospital outpatients in the hospital, including in provider-based departments of the hospital on the order of a physician and under the direct supervision of a physician could be paid under Medicare Part B to a

hospital because hospitals may determine the staff who furnish services, taking into consideration the CoPs state laws and hospital policies.

Note that an applicable waiver under section 1135(b)(2) would permit -- for Medicare billing purposes -- health care practitioners with equivalent licensing in another State to provide services in an affected State in the emergency area without a license, so long as they are not affirmatively barred from practice in the affected State or in any other State a part of which is included in the emergency area.

- F. If nursing home patients require admission to a hospital for minor acute illness, can they be admitted to an alternative care site? Can the alternative care site be reimbursed?

Nursing homes “must provide services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.” We do not believe the criteria for admission to a hospital would change during an H1N1-related emergency. For example, if a resident fell and needed stitches, the resident could be treated at an urgent care facility. To the extent that residents are admitted to an alternative care site that is provider-based to a hospital, the hospital would receive payment for services rendered to a Medicare or Medicaid beneficiary as it would for admission to the main hospital in the absence of an emergency. Other types of alternative care sites can receive reimbursement if they meet the criteria for reimbursement as another type of provider or supplier, have been enrolled in the Medicare program, and, in the case of institutional providers/suppliers, have been certified as meeting Medicare health and safety standards (the CoPs or Conditions for Coverage, as applicable).

- G. If home health patients become ill and are admitted to an alternative care site and then readmitted back into homecare, will this care be reimbursed?

With respect to Medicare FFS, it would depend upon the alternative care site. For home health purposes, a beneficiary’s “home” is any place in which a beneficiary resides that is not a hospital, skilled nursing facility (SNF), or nursing facility as defined in section 1861(e)(1), section 1819(a)(1), or section 1919(a)(1) of the Act, respectively. In an extraordinary circumstance of a declared emergency or disaster, a place of residence can include services provided at temporary locations like a family member’s home, a shelter, a community facility, a church, or a hotel.

Currently, home health patients may be admitted to an inpatient hospital setting and readmitted back into home health care. The reimbursement for this situation would remain the same in an emergency situation. A partial episode payment (PEP) adjustment is made when a patient elects to transfer to another home health agency (HHA) or is discharged and readmitted to the same HHA during the 60-day episode. The PEP adjustment is determined by proportionally adjusting the original 60-day episode payment to reflect the length of time the patient remained

under the HHA's care before the intervening event. If a patient experiences an intervening event and is returning to the same HHA, the HHA has the choice either to discharge and readmit the patient, or to keep the patient's home health episode open (not discharging the patient). If the patient is discharged and readmitted to the same HHA, then that HHA's previous episode is PEP'd, and the HHA is paid a Request for Anticipated Payment (RAP) of 50% of the Home Health Resource Group (HHRG) payment determined for the subsequent home health episode. If the PEP is a result of the patient electing a transfer to another HHA, the earlier episode is PEP'd and the HHA to which the patient has been transferred is paid a RAP of 60 percent of the HHRG payment determined for the subsequent home health episode. Note that a PEP adjustment can be made when a patient elects transfer to another home health agency, or returns to the same HHA after a discharge during the same 60-day episode. In the case of a patient returning to the same HHA in a 60--day episode, it doesn't matter where the patient went during the break.

- H. Will the claim filing deadline be extended so that the clock starts after the disaster or emergency is declared over?

Medicaid: With respect to Medicaid claims, States, under 42 CFR § 447.45(d) require that providers submit claims no later than 12 months from the date of service. Health care providers should work with their States to determine if there are any other State requirements related to claim submission and whether there are any exceptions allowed. With respect to States claiming Federal matching funds, States have two years from the date of the State's expenditure to file a timely claim for FFP. 45 CFR 95.19(d) permits a timely filing exception to any claim for which the Secretary decides there was good cause for the State's not filing it within the time limit.

Medicare: Under FFS, the timely claim filing requirement specified by regulation at 42 C.F.R. § 424.44 can be waived only for error or misrepresentation (as discussed more fully in the regulation itself). Moreover, a waiver or modification of Medicare program requirements in accordance with section 1135 of the Act (such as a modification of timely filing requirements) is generally only in effect for up to the duration of the declared emergency period, not after the period has ended. Nevertheless, because the timely filing window is a minimum of 15 months – to as much as 27 months depending on when the service was furnished – CMS does not expect that providers affected by an emergency/disaster would likely be adversely affected by the timely filing requirement.

- I. Will CMS consider periodic interim payments to providers as a means of ensuring cash flow?

Medicaid: States have great flexibility in developing payment methodologies for providers, which can include interim payment methodologies that provide for payments on an ongoing basis as services are furnished, subject to reconciliation

with the approved payment rates. Current Medicaid requirements do not allow “pre-payment” for services that have not actually been furnished. CMS will continue to provide ongoing technical assistance to States regarding appropriate reimbursement methodologies.

Medicare: CMS believes accelerated payments (Part A) or advance payments (Part B) would be a better means of ensuring continued cash flow. Policy and procedures on advance and accelerated payments are tied to the expectation that claims or bills are forthcoming; the delay is temporary and accelerated and advance payments are simply that -- “advanced” funds with the expectation that bills will be used to offset the advance. Medicare’s mission is to reimburse for covered Medicare services. Therefore, Medicare billings are critical to its mission. In the event of an emergency or disaster, for providers who are still rendering some services or who are taking steps to be able to render services again, accelerated or advance payments may be available. Providers in this position should contact their fiscal intermediary, carrier, or Medicare Administrative Contractor (MAC) for details.

- J. Will the medical records documentation requirements be modified after declaration of a disaster or emergency?

Medical record documentation requirements are critical components of patient safety, the Medicare claims payment processing system and Medicare payment policy. Medicare providers are required to maintain adequate documentation to support the provision of care and payment for reasonable and medically necessary Medicare covered services. Medicare contractors are required to pay claims that meet the published criteria for payment, including medical record documentation. However, CMS acknowledges that in unusual situations such as natural disasters, providers may not have documentation immediately at hand. CMS has outlined policies on administrative relief from medical review in the Program Integrity Manual (CMS Pub. 100-8), Chapter 3, Section 3.2.2.

With respect to Medicare patient health and safety standards, absent a section 1135 waiver, health care facilities will still be expected to maintain medical records on each patient. Care in progress is dependent upon a complete and accurate medical record. If there is an applicable section 1135 waiver in place, then medical record standards may be relaxed, but facilities would still be expected to make reasonable efforts to maintain a medical record to support safe patient care. For example, in situations where the patient is evacuated to other care locations, facilities would still be expected to make reasonable efforts to ensure that a patient’s medical records remain with the patient.

- K. Will CMS provide some flexibility with coding for Medicare claims after a disaster or emergency has been declared?

With respect to Medicare fee-for-service (FFS), the HCPCS Level II code set includes a modifier “CR” (“CATASTROPHE/DISASTER RELATED”). This modifier was implemented after Hurricane Katrina, and remains in the HCPCS code set to be activated for claims processing for whatever reason and time period is prescribed in the event of a future disaster. Similarly, the “DR” condition code is available for institutional billers to indicate that an entire bill is “disaster related.” Providers would continue to be required to follow correct coding principles and existing CMS instructions in order to ensure appropriate payment. Claims processing edits would remain in place, as these edits ensure that payment is made consistent with all statutory and regulatory requirements, including the bundling of payment for certain services.

Medicare FFS claims processing systems are designed to ensure that Medicare pays for appropriate services. Providers have a key responsibility in this system to ensure that they accurately code for the services they provide. In the current Medicare claims payment system, it is generally not possible to pay claims that are not properly coded. Implementing changes to system edits would require extensive systems changes that could require several months to implement. Implementing edit changes indiscriminately would increase the financial vulnerability of the Medicare program.

II. Conditions of Participation at alternative care sites

- A. Is CMS able to relax the standards for compliance with hospital or CAH CoPs for alternate care sites so that these alternate sites can be reimbursed for services provided to beneficiaries without a section 1135 waiver in effect?

While the availability of certain flexibilities, whether under existing regulations or a section 1135 waiver, depends upon the specific facts and circumstances arising in an emergency, the discussion below attempts to anticipate a variety of potential issues and address them separately.

No section 1135 waiver currently in place

In general, no Medicare CoPs can be “relaxed” unless the Secretary invokes her authority under section 1135 of the Act, and applicable CoPs are temporarily waived or modified there consistent with section 1135(b)(1)(A) of the Act. There are some specific independent waiver authorities for CoPs that do not require operation of section 1135 (for instance, with respect to adherence to the Life Safety Code), and some waivers concerning professional staffing levels for certain types of facilities in areas experiencing a shortage of those professionals but we do not believe that these authorities are specifically relevant to the question of alternative care sites in connection with a pandemic.

1. Increasing a hospital’s or CAH’s inpatient capacity in the absence of an applicable section 1135 waiver

(a) Actions permitted:

- (i) A hospital or CAH may evaluate current inpatients to determine whether it would be clinically appropriate to discharge any of them earlier than would ordinarily be the case, to a lower level of care; such as SNF or home health. We note, however, that for Medicare beneficiaries, the requirement for a SNF stay to be preceded by a hospital stay of at least 3 days may pose a challenge to accelerated discharge (unless CMS has waived that requirement for beneficiaries in the affected area under its authority in section 1812(f) of the Act).
- (ii) A hospital that has a Medicare certification for additional bed capacity in its physical plant (beyond those in place at the time of the emergency) may increase the number of inpatient beds that it is maintaining. Since many hospitals already have more beds certified for Medicare than they actually maintain, this could be done without Medicare review and approval. If the increase were to exceed the number of presently Medicare-certified beds, the hospital would be expected to file an amended Form CMM 855A with its Medicare Administrative Contractor (MAC) or legacy fiscal intermediary (FI) as soon as possible. CMS has the discretion to not require a survey of the additional beds for CoP compliance. (Note that the hospital must comply with any applicable State law or regulations governing an increase in beds.)
- (iii) A hospital may add a remote location that provides inpatient services to the hospital's Medicare certified beds under its existing provider agreement, provided that the remote location satisfies the requirements to be provider-based to the hospital's main campus (including being located within 35 miles pursuant to 42 CFR 413.65(e)(3)). The remote location must satisfy all provider-based requirements including being compliant with the hospital CoPs. The hospital would be expected to file an amended Form CMS 855A with its MAC or legacy FI as soon as possible adding an additional location. CMS generally requires a survey of compliance with all CoPs at all new inpatient locations, but also has discretion to waive the onsite survey in this area.

(b) Actions Not Permitted:

- (i) A CAH that has excess bed capacity in its physical plant may not increase the number of inpatient beds it is maintaining beyond 25 beds, since this limit is established in Medicare statute.

- (ii) A hospital or CAH that has a separately Medicare-certified SNF on its campus may not place patients requiring inpatient hospital care in the SNF. (Hospitals and CAHs certified for swing-beds may take advantage of existing flexibility to use beds for either acute or SNF-level inpatient care.)
 - (iii) A hospital with an Inpatient Prospective Payment System (IPPS)-excluded unit or a CAH with a distinct part psychiatric or rehabilitation unit may not use beds in those units without jeopardizing the ongoing excluded status of those units.
 - (iv) A hospital or CAH may not provide inpatient services in a remote location that cannot meet the hospital provider-based requirements, including hospital or CAH CoPs – e.g., a public armory, school gymnasium, etc.
2. Increasing a hospital's or CAH's outpatient capacity in the absence of a section 1135 waiver
- (a) Actions Permitted:
 - (i) Under the Medicare program hospitals and CAHs already have considerable flexibility to add sites of care that would be considered part of the hospital, under the provider-based regulations. If such additional locations are on the hospital's main campus, the hospital may operate the site without any notice to CMS. If the site is off-campus, the hospital would be expected to file an amended Form CMS 855A as soon as reasonably possible with its MAC/legacy FI. The hospital is responsible for complying with all hospital CoPs and the provider-based regulations. (Provider-based requirements can be complex, and include such things as full integration of the site into the hospital's administrative, financial, and clinical operations; exclusive use of the site for hospital operations; holding the site out to the public as part of the hospital; etc.) For CAHs, there are additional restrictions governing off-campus care sites, i.e., each of those sites must satisfy the CAH statutory requirements to be located more than a 35-mile drive (or in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from another hospital or CAH.
 - (ii) Such alternative care sites on a hospital or CAH's main campus could include tents, parked mobile units, or other facility-based treatment areas. Use of tents would be expected to be a temporary rather than a permanent measure, but would be permissible. Hospitals and CAHs must ensure that all care locations comply

with State licensure rules and the applicable Medicare hospital or CAH CoPs. When the alternative care sites are off the hospital's or CAH's main campus, the hospital must also comply with Medicare rules governing off-campus departments that are treated as part of the hospital (the provider-based rules).

(b) Actions Not Permitted:

- (i) Off-campus alternative care sites that do not meet the provider-based requirements and/or the hospital or CAH CoPs may not be treated as part of the hospital.

Section 1135 Waiver Available

1. Increasing a hospital's or CAH's inpatient capacity when there is a section 1135 waiver in effect for the geographic area in which the hospital or CAH is located.

(a) Actions Permitted:

- (i) All of the actions listed above that are permitted without a section 1135 waiver.
- (ii) When the appropriate section 1135 waivers are in place, a CAH that has excess bed capacity in its physical plant may increase its number of inpatient beds above 25 for up to the duration of the waiver period.
- (iii) If a section 1812(f) waiver is also in effect, the 3-day prior hospital stay requirement for a SNF stay can be temporarily relaxed, and a Medicare beneficiary's care will be reimbursed at the appropriate SNF PPS rate. This may make it easier for a hospital or CAH to discharge certain Medicare beneficiaries. Section 1812(f) of the Act allows Medicare to pay for SNF services without a preceding 3-day qualifying hospital stay if the Secretary of HHS finds that doing so will not increase total payments made under the Medicare program or change the essential acute-care nature of the SNF benefit. This policy applies to any Medicare beneficiary who:
 - Was evacuated from a SNF in the emergency area;
 - Was discharged from a hospital (in the emergency or receiving locations) in order to enable the hospital to provide care to more seriously ill patients; or
 - Needs SNF care as a result of the emergency, regardless of whether that individual was in a hospital or SNF prior to the disaster.

Note that in cases where we have determined that a waiver under section 1812(f) is appropriate, we generally have applied the waiver of the requirement for a 3-day hospital stay to the geographic areas and timeframes specified in the Secretary's waiver or modification of requirements under section 1135 of the Act. However, unlike the policies implemented directly under the section 1135 waiver authority itself, those implemented under authority of section 1812(f) need not be limited to those disaster-related relocations that occur *within* the designated emergency areas. Instead, they would apply to all beneficiaries who are evacuated from an emergency area as a result of the disaster, regardless of where the "host" SNF providing post-disaster care is located.

- (iv) When the Secretary has authorized appropriate waivers under section 1135 of the Act, and there has been a determination that such waivers are necessary, a hospital that also has a hospital-based SNF on its campus potentially could expand its inpatient bed capacity by placing some hospital patients into its hospital-based SNF. Although the availability of 1135 waivers would depend upon the facts and circumstances of the emergency, in past emergencies, under the section 1135 waiver authority, we have allowed such an increase in inpatient bed capacity for up to the duration of the waiver period, so long as the hospital documented that those patients admitted to the hospital-based SNF need a hospital level of care and provided adequate RN staffing in the SNF to make sure that every patient needing a hospital level of care has immediate RN availability at the bedside. However, even under such a waiver, high acuity hospital patients or patients who need special equipment or special treatments should not be placed in the SNF. Further, care must also be taken not to place hospital patients into the SNF if those patients would place the existing SNF patients at risk (behavior problems, communicable infections). When an appropriate section 1135 waiver has been in place for this purpose, the hospital has been permitted to bill at the IPPS rate for the stay of hospital patients temporarily located in the SNF beds. Should a hospital receive such a waiver, the hospital would need to keep good records for billing and for cost reporting reasons. Since the hospital and its hospital-based SNF share a cost report, costs would need to be appropriately attributed.
- (v) The same principles have been applied in past emergencies when a hospital has sought to increase its inpatient short-term acute care beds by utilizing beds in an IPPS-excluded rehabilitation or psychiatric unit, i.e., this has also required an applicable section 1135 waiver, and as a condition of the waiver, we required that appropriate care would have to be provided, and careful

consideration must be given to the appropriateness of placing the acute inpatients in the excluded unit. For example, placement of a medical/surgical inpatient in a locked, involuntary psychiatric unit would not be appropriate.

- (vi) Although the specific implementation of a section 1135 waiver for alternative care sites will depend upon the facts and circumstances of the emergency, when section 1135 waiver authority applicable to alternative care sites is in place and an individual provider is seeking an alternative care site waiver (e.g., to establish a temporary remote location in a site that does not meet the provider-based and CoP requirements, such as a gymnasium or hotel), our past practice has been to require the provider to contact its State Survey Agency (SA) for each proposed alternative care site placement, to request an 1135 waiver from specific Federal health and safety standards as needed, detail what services it planned to offer at the alternative site, and how it intended to ensure the health and safety of patients or residents at that site. In past emergencies, the SA has forwarded such requests to the appropriate CMS Regional Office, which has made case-by-case decisions for approving alternative care sites for up to the duration of the waiver period and monitored the situation closely until the 1135 waivers expire. We would expect that in future emergencies we would use a similar process to expedite approval of alternative care sites.

2. Increasing a hospital or CAH's outpatient capacity under an applicable section 1135 waiver.

(a) Actions Permitted:

- (i) All of the actions listed above that are permitted without a section 1135 waiver.
- (ii) Although the specific implementation of a section 1135 waiver for alternative care sites will depend upon the facts and circumstances of the emergency, when section 1135 waiver authority applicable to alternative care sites is in place and an individual provider is seeking an alternative care site waiver to establish temporary off-campus service sites in facilities that do not satisfy the either the provider-based or CoP requirements, e.g., gymnasiums, schools, malls, etc., our past practice has been to require the provider to contact its State Survey Agency (SA) for each proposed alternative care site placement, to request an 1135 waiver from specific Federal health and safety standards as needed, detail what services it planned to offer at the alternative site, and how it intended to ensure the health and safety of patients or residents at that site. In

past emergencies, the SA has forwarded such requests to the appropriate CMS Regional Office, which has made case-by-case decisions for approving alternative care sites for up to the duration of the waiver period and monitored the situation closely until the 1135 waivers expire. We would expect that in future emergencies we would use a similar process to expedite approval of alternative care sites.

III. Standards of care in alternative care sites

- A. Has CMS discussed issues related to an altered standard of care environment where providers with usual requirements of care will have to be accommodated in a resource constrained environment?

CMS does not dictate “standards of care” with respect to the practice of medicine, and thus has no comment to the extent the question concerns the way in which physicians practice medicine. However, to the extent that CMS can provide information with respect to our approach to assessing provider compliance with Medicare requirements in an emergency that may put additional strain on provider resources, we provide the response below.

Medicare establishes health and safety standards for health care facilities, (such as hospitals), and we outline below some potential flexibilities for complying with those standards in an emergency.

No section 1135 waiver in place

Even when there is no section 1135 waiver in place, it is possible for health care facilities to operate in a scaled down manner and remain in compliance with CoPs. Medicare health and safety standards are generally broad and flexible and scalable, since they have to be applicable to facilities ranging from 30-bed hospitals, to 500-bed hospitals. Experience has shown that in response to a localized disaster or emergency, acute care facilities typically scale down certain services accordingly, eliminating or drastically reducing elective services and focusing on providing safe care for inpatients who cannot be discharged, and providing emergency care. Some scaling back can be accomplished within the existing regulatory framework, without a need for a section 1135 waiver, but the nature of such “scaling back” is obviously fact-dependent.

If compliance issues come up in such localized situations where no applicable section 1135 waiver is available, CMS focuses on fundamentals, such as assuring medical and nursing staff have proper credentials and, in the case of medical staff, have privileges; assuring that care is safe, that patients’ rights are protected and that medical records with sufficient information to promote safe care are maintained. Additionally, for facilities subject to the Life Safety Code (LSC), past experience has demonstrated that many facilities, even when functioning in a

degraded status, or in the case of the establishment of alternative care sites, may continue to meet the LSC by implementing reasonable and prudent measures. For example, there were several hospitals that were damaged by Hurricane Katrina which continued to comply with the LSC by implementing reasonable and prudent measures, and therefore were able to continue operations in a degraded but safe environment for weeks or months until repairs could be completed. With regard to the provision of hospital or CAH emergency services, EMTALA imposes certain requirements. We have developed a fact sheet to describe EMTALA-compliance alternatives available to hospitals without a section 1135 waiver. The Fact sheet can be found at the following website:

http://www.cms.hhs.gov/SurveyCertificationGenInfo/downloads/SCLetter09_52.pdf

Section 1135 waiver in place

If the Secretary determines that section 1135 waivers are appropriate and has delegated implementation of such waivers to CMS, CMS may authorize waiver of specific Medicare health and safety standards for individual providers or groups of providers for up to the duration of the waiver period. When such waiver authority is in place and an individual provider is seeking specific waivers, in past emergencies we have required the provider to contact its State Survey Agency (SA) to request a waiver from specific Federal health and safety standards as needed, detailing how it intends to ensure the health and safety of patients or residents under the relaxed standards. The SA has then forwarded the request to the appropriate CMS Regional Office, which, depending on the scope and severity of the emergency, has generally made case-by-case decisions for approving the waivers. The SA has monitored the situation closely until the waivers expire. We would expect to use a similar process in future emergencies to implement an applicable section 1135 waiver.