The Centers for Medicare and Medicaid Services (CMS) has within its authority to manage the Medicare, Medicaid and SCHIP programs, a number of statutory, regulatory and other policy flexibilities to help ensure protection of health and safety of patients and residents in the face of potential disruptive events. These range from some degree of flexibility under existing statutory or regulatory authorities, including discretion on directing use of its resources, and ability to invoke its Demonstration authority, up to the additional flexibilities offered under Section 1135 (b) of the Social Security Act, which allows certain requirements to be waived or varied during the time of a Public Health Emergency (PHE), as declared by the U.S. Secretary of Health and Human Services, under section 319 of the Public Health Service Act.

## 1115 Katrina Waiver Demonstration / Uncompensated Care Pool (UCCP)

CMS approved 32 state requests for section 1115 demonstration program waivers, and issued grants to States for Federal payments for Medical Assistance for Hurricane Katrina relief under the Deficit Reduction Act (DRA). CMS provided flexibility for individuals to enroll into Medicaid/SCHIP for up to five months without requiring the usual documentation. This allowed temporary Medicaid coverage to individuals evacuated from disaster declared counties and parishes. (NOTE: After the five month period, individuals would have needed to reapply for coverage using normal standards.)

Additionally, in 8 of the 32 States approved, CMS approved provisions for an uncompensated care pool program, allowing health care providers who had incurred uncompensated care costs providing medically necessary services through the period of the declared PHE, for Katrina evacuees without health insurance coverage, to be reimbursed.

#### Hospitals

If a Hospital did not have any medical records available because of a disaster, CMS took a liberal view of the situation during the time of the PHE. However, as in physician attestations, the new record would have to reflect the lack of prior documentation.

CMS would allow hospitals in a PHE area to be given temporary certification to perform organ transplants as a transplant center under special circumstances, and only for as long as the PHE existed, or (with State and/or Regional Office approval) until the transplant center was ready to relocate from a temporary location to a permanent location. Waiver of the standard certification and survey process would be considered on a case-by-case (i.e., center-by-center) basis.

# Expand Availability of Inpatient Beds

To expand the availability of inpatient beds and ensure that patients could have access to needed inpatient care, CMS waived or offered to waive many of Medicare's classification requirements, allowing specialized facilities and hospital units to treat patients needing inpatient care. For example...

- Not counting any bed use that exceeded the 25-bed or 96-hour average length of stay limits for critical access hospitals (CAHs) located in PHE States, if such use was related to the hurricane.
- Not counting admissions to inpatient rehabilitation facilities (IRFs) located in the PHE States toward compliance with the 75 percent rule if such admissions were related to the hurricane.
- Not counting patients admitted to a long-term care hospital (LTCH) located in the PHE States toward the calculation of the facility's average length of stay if such admissions were related to the hurricane.
- Allowing beds in a distinct psychiatric unit in an acute care hospital located in the PHE States to be available for patients needing inpatient acute care services if such use was related to the hurricane.
- Allowing a hospital with less than 100 beds and located in a non-urbanized area to apply for swing bed status and receive payment for skilled nursing facility services on a case-by-case basis
- Allowed hospitals to convert exempt beds to acute care beds to accommodate the needs of disaster victims on a case-by-case basis.

## **Emergency Medical Treatment and Active Labor Act (EMTALA) Sanctions**

Sanctions under EMTALA for redirection of individuals who receive medical screening, exams or transfer were made available for waiver as needed, to States affected by Hurricane Katrina. For example, if evacuees from states affected by the PHE, arrived at hospital emergency departments merely to obtain refills of prescriptions that they lost when they evacuated during a disaster or PHE, then in general, a full medical screening examination for such a patient was not required during the time of the PHE. EMTALA regulations make it clear that individuals seeking only prescription refills need not be given a complete medical screening examination, but rather, one that is appropriate for the request that they make. Hospitals could develop specific protocols that included a streamlined screening examination for patients seeking prescription refills, consistent with the regulation cited above.

### **Critical Access Hospital (CAH)**

During the declared PHE, CMS permitted affected CAHs to exceed the 25-bed or 96-hour average length of stay limits, if this result was clearly identified as relating to the disaster. CAHs were required to clearly indicate in the medical record where an admission was made or length of stay extended to meet demands of the crisis.

## End Stage Renal Disease (ESRD)

Medicare provides for an immediate, 8-month "special purpose dialysis facility" classification for facilities that provide dialysis treatment services during emergencies. This facility may provide services only to those patients who would otherwise be unable to obtain treatments in the geographical areas served by the facility.

Renal transplant patients or patient candidates relocated to other transplant centers because of a PHE were allowed to transfer their accumulated waiting time without losing any allocation priority.

## Medicare Advantage and Medicare Prescription Drug Plans

CMS permitted Medicare Advantage enrollees to use out-of-network providers during the PHE.

CMS established a special enrollment period (SEP) for all Hurricane Katrina evacuees that gave them more time to change their Medicare prescription drug plans (NOTE: the newly created Medicare Part D benefit was established for the first time effective January 1, 2006, which was part of the time period covered by the PHE). For the SEP, Medicare beneficiaries were considered "evacuees" and eligible for this SEP if they resided in any of the zip-codes declared as being eligible to receive "individual assistance" by FEMA, at the time of the onset of the hurricane, in August 2005.

CMS established policy guidance for Medicare Parts C and D plans providing prescription drugs to assure access to covered medications during times of potential or realized disasters. Essentially, during any public health disaster or PHE declaration, where beneficiaries are displaced from their place of residence and cannot be reasonably expected to obtain covered Part D drugs at a network pharmacy, plans will be required to assure that their enrollees have adequate access to drugs dispensed at out-of-network pharmacies. Similarly, if the nature of the disaster requires voluntary or mandatory evacuation, plans will be required to guarantee immediate refills of Part D medications to any beneficiary located in an "emergency area" defined as the area in which there has been a Stafford Act or National Emergencies Act declaration and a PHE declaration. In conjunction with this guarantee CMS would expect all "refill too soon edits" to be removed.

## Nursing Homes (NHs) / Skilled Nursing Facilities (SNFs) / Nursing Facilities (NFs)

CMS would allow many requirements to be waived that facilitate a smooth transition for residents that would fit their individual care needs. For example, CMS understood that it might be difficult to determine whether the 3-day prior stay requirement had been met. This policy applied to any Medicare beneficiary: • evacuated from a NH in the emergency area,

• discharged from a hospital (in the emergency or receiving locations) in order to provide care to more seriously ill patients, or

• who needed SNF care as a result of the emergency, regardless of whether that individual was in a hospital or nursing home prior to the disaster. Providers must document in the medical record both the

medical need for the SNF admission and how the admission was related to the crisis created by the declared PHE and its aftermath.

Minimum Data Set (MDS) requirements relating to admissions, were modified as follows:

- In the case of evacuations, the evacuating facility needed to determine by day 15 whether or not residents would be able to return to the evacuating facility within 30 days from the date of the evacuation. In the case that the evacuating facility was unavailable to make this determination, the receiving facility would need to make this determination.
- When the residents returned to the evacuating facility within 30 days, the MDS cycle continued as though the residents were never transferred. This decision placed minimal disruption on the staffs' daily routine in caring for all residents. The originating facility would then complete MDSs according to the Long Term Care Facility Resident Assessment Instrument User's Manual once the residents returned to the evacuated facility.
- When the evacuating and/or receiving facility determined that the residents would not be
  returning to the evacuating facility within the 30-day time frame, the evacuating provider needed
  to discharge the resident by completing a discharge tracking form whenever possible. The
  receiving facility would admit the residents and complete an admission MDS (and/or a 5-day
  MDS) as per the Federal participation requirements. The MDS cycle would then begin as of the
  admission date. The discharge/admission date needed to occur within the previously mentioned
  30-day time frame.
- When the resident returned to the evacuating facility after the 30-day time frame, the receiving facility would discharge the resident and complete a discharge tracking form. The evacuating facility would re-admit the resident. The MDS cycle would be established based on the reentry tracking form.
- When patients were transferred to a second facility with an anticipated return to the evacuating facility within the 30-day time frame, the evacuating facility could bill Medicare for the services using the evacuating facility's provider number. The evacuating facility was responsible for payment to the receiving facility for the services that facility provided to the evacuated patients. In these cases, the fiscal intermediary processed these claims using the evacuating facility's provider number as if the patients had not been transferred.

If during a disaster, the electronic MDS submission was not possible from the evacuated facilities (e.g., server was down or equipment had water damage, or was otherwise destroyed or lost), CMS offered to help the evacuated facility restore previously submitted MDS data once a working computer could be obtained.

CMS allowed increases to licensed and Medicare certified nursing home bed capacity on a case-by-case determination. While facilities were permitted to exceed their census to meet a short-term need, continued housing of residents over a facility's capacity had to be evaluated by the State Survey Agency to ensure that staffing levels were sufficient, as well as the ability to safeguard residents.

If a resident was discharged from an evacuating facility within the 30 days limit, the MDS cycle would be allowed to continue as though the resident had never been transferred.

CMS determined it would not consider a NF or a State out of compliance if documentation showed that due to emergency evacuation, a resident's possible need for RR (Resident Review) was known at admission, was initiated not later than the initial resident assessment and MDS process, and the evaluation/determination was performed as soon thereafter as resources were available.

Where there was no interstate Preadmission Screening and Resident Review (PASRR) agreement between the sending and receiving States, the State of residence would normally have responsibility to pay for PASRR functions, or have a reciprocal agreement with the receiving State. Depending on the number of evacuated NF residents, and the length of stay, States could make retroactive inter-state PASRR agreements.

CMS recommended that nursing homes must do the best they could to ensure that only nurse aides in

good standing, who have relocated from an affected area, were hired to work during the disaster. At a minimum, CMS expected nursing homes that employed nurse aides relocating from an affected State, to search any nurse aide registry that the nursing home believed might contain information on the nurse aide. The Office of Inspector General (OIG) Exclusion List was also offered as a useful tool for nursing homes and other healthcare providers to obtain information about nurse aides and other health care workers with relevant convictions, such as offenses of abuse and neglect. The OIG Exclusion List may be located at: <a href="http://oig.hhs.gov/fraud/exclusions/listofexcluded.html">http://oig.hhs.gov/fraud/exclusions/listofexcluded.html</a>

### Home Health Agencies (HHAs)

The comprehensive assessment requirement at 42 CFR 484.55 was modified by CMS, as follows, in Medicare HHAs serving qualified home health patients in PHE areas determined by the Secretary: • The Start of Care assessment (RFA 1) could be abbreviated to include the Patient Tracking Sheet and the 24 payment items.

• The Resumption of Care assessment (RFA 3) and the Recertification assessment (RFA 4) could be abbreviated to the 24 payment items.

• The Discharge assessment (RFA 8 or RFA 9) and the Transfer assessment (RFA 6, RFA 7) were temporarily suspended.

NOTE: HHAs needed to maintain adequate documentation to support provision of care and payment.

The HHA's abbreviated assessment as described above did not have to meet the 5-day completion date or the 7-day lock date. In addition, the OASIS transmission requirements at 42 CFR 484.20 were suspended for those Medicare approved HHAs that were serving qualified home health patients in the affected areas. HHAs were expected to use this policy only as needed, and to return to business as usual as soon as possible

## **Community Mental Health Center (CMHC)**

CMS allowed the on-site review requirement for CMHC applicants during a PHE to be deferred, (NOTE: CMS determined that all other CMHC requirements had to be met (i.e., core requirements, operational for at least one business quarter, etc.) at the time of its RO deferral decision. Continued certification was dependent upon a satisfactory on-site visit by CMS staff, once travel to the affected area was feasible.) CMS ROs allowed affected CMHCs to temporarily relocate their practice on a case-by-case basis,

subject to review within six months to determine continued need for the temporary site.

CMS allowed the 24-Hour Emergency Phone Service requirement for CMHC providers to be waived if phone service was disrupted in the PHE area, and if all other core requirements were met by the new CMHC applicant. (NOTE: if the CMHC is found to be out of compliance with this requirement, once phone service was restored, its certification would be terminated.)

## **Clinical Laboratory Improvement Plan Amendment (CLIA)**

As necessary, CMS-certified laboratories located in a declared PHE area were allowed to be inspected as timely as possible and as State Agency resources were sufficiently available. The order of priority for inspections was to be: complaints, followed by laboratories whose certificates were expiring, and then new laboratories requiring initial certification inspections.

CMS used discretion in exercising its enforcement authority during the disaster recovery period as necessary to take into account unusual circumstances under which labs were operating. CMS made those labs with pending enforcement actions that constituted "immediate jeopardy" to patient health and safety, to be the 1<sup>st</sup> priority.

## Physician Self-Referral

On a case-by-case basis and/or through guidance posted on the CMS website, CMS allowed sanctions for violations of the physician self-referral (Stark) law to be waived for practices that otherwise would not meet the specific criteria for an exception, provided that such arrangements did not lead to program or patient abuse, and that other safeguards which may be applicable to the specific arrangements under consideration, existed. The included hospitals providing free office space, or low interest or no interest loans, or offering certain arrangements to physicians who were displaced by the hurricane. The Stark

waiver was available only to those PHE States severely impacted by Hurricane Katrina and only during the time that the PHE was in effect.

Adjust and Coordinate Quality Assurance Oversight and Mobilize Survey & Certification resources

CMS made key MDS information available electronically to receiving nursing homes (NHs) where Katrina evacuees were relocated (via the Minimum Data Set) and worked with State officials to make pharmacy information available.

CMS quickly issued communications to all State Survey Agencies providing appropriate discretion in both evacuation and relocation to assure beneficiary protections but also to afford the flexibility needed in an emergency situation, and posted detailed "Question & Answer" documents on the CMS website.

CMS suspended certain restrictions on providers to enable them to accept evacuees

State Survey Agency and CMS partnerships were an important and crucial part of both the response and recovery phases of the disaster. As the staff of one State Survey Agency staff were needed to provide care to evacuees in special need shelters, the CMS Regional Office stepped in to provide critical survey and certification monitoring and enforcement activities. Hurricane Katrina demonstrated the importance of partnership with State Agencies as contacts for communications, advocates/links for resources, and facilitators for the provision of health care for all of those in need of care.

CMS worked closely with State Survey Agencies and the Accrediting Organizations to conduct required surveys in a prompt and coordinated fashion in the all-year recovery efforts as providers sought to reconstitute themselves (sometimes moving 2, 3, or 4 times in the process).

In partnership with States, CMS acted to speed the provision of health care services to the elderly, children, and persons with disabilities by relaxing normal operating procedures until providers could reasonably be expected to continue under the normal requirements. CMS worked closely with State Medicaid Agencies to coordinate resolution of interstate payment agreements for recipients served outside their home states.

In light of the Gulf Coast's very fragile health care infrastructure's ability to meet the needs of its returning population, CMS conducted joint weekly teleconferences for approximately 6 months between its central and regional offices, the affected State Survey Agencies, the Joint Commission (JC), and local hospitals and other health care providers, on an invitational basis. This was done to: coordinate monitoring of local provider conditions as they emerged and potentially impacted on rules for participation in Medicare; reduce any undue burden caused by joint jurisdiction; and facilitate timely reporting and communications.

CMS quickly established multiple strategies to communicate with affected providers about the changes. For instance, CMS posted Question and Answer documents on CMS' website; held special "Open Door Forums;" and arranged meetings and regular phone calls with affected states, national and state provider associations, and individual providers.

CMS partnered with States and the US Health Resources and Services Administration (HRSA) to resolve licensing and credentialing issues for Inactive Reserve Corp (IRC) officers and volunteers from other grantees.

# **Enforcement Activities**

ROs used discretion to act on State Survey Agency recommendations to defer certain pending enforcement actions *on a case-by-case basis* during Hurricane Katrina, for example:

(a) For providers directly impacted by a PHE, generally, civil money penalties (CMPs) were not collected during the emergency period, and accrual of penalty amounts would temporarily cease during the PHE.
(b) For all providers that had admitted evacuees where CMPs had also been imposed, the ROs used discretion to handle CMP issues on a case-by-case basis.

(c) For other providers that might have been affected by the inability of the SAs to conduct revisit surveys, the ROs could make a case-by-case determination.

CMS generally would suspend collection of a CMP for nursing homes (NHs) located in a declared PHE area providing care for evacuees. Subsequently, CMS requested a financial impact statement from the

specific NHs where CMPs were due and payable, and would determine case-by-case, if any adjustments should be made. Suspension of CMP collection for any other NH provider admitting evacuees would be handled on a case-by-case basis.

### **Other Provider Certification**

If the nature of a PHE would have necessitated a provider/supplier to reopen in a new location, CMS used discretion to determine if the current provider's relocation or cessation of business at an original location and establishment of a new business at another location, demonstrated that it was functioning as essentially the same provider serving the same community. CMS considered each request for relocation on a case-by-case basis

### **Graduate Medical Education (GME)**

CMS published a GME interim final rule (with comment) on April 12, 2006, in order to accomplish most of the goals necessary to occur due to the crisis created by Hurricanes Katrina and Rita. The rule went into effect upon publication.

On June 30, 2006, CMS released a final GME rule that responded to numerous comments notifying CMS that many hospitals would find it difficult to meet the submission deadline for the emergency Medicare GME affiliation agreements due in 2006 and revised the deadline for submission of the emergency Medicare GME affiliation agreements due in 2006. Under that final rule, the 2006 deadlines to submit these special emergency affiliation agreements were changed to on or before October 9, 2006.

In addition, on November 27, 2007, CMS issued another GME interim final rule (with comment) in order to extend the effective period for emergency affiliation agreements under certain conditions from 3 years to 5 years and provide for retroactive written agreements to allow hospitals to be paid for the training of their residents sent to non-hospital sites after Hurricanes Katrina and Rita. The provisions in this second interim final rule were effective immediately on the date of publication.

Medicare billing and other requirements and accelerated payments

To accommodate the emergency health care needs of beneficiaries, CMS moved quickly to support efforts of the health care community. During the time of the PHE, CMS temporarily relaxed Medicare fee for service (FFS) policy, billing and other requirements and offered accelerated payment options for hospitals and other providers furnishing such care. For example,

- CMS allowed hospitals to have a responsible physician at the hospital (e.g., chief of medical staff or department head) to sign an attestation when the attending physician could not be located.
- CMS allowed providers affected by the hurricane to file paper claims if necessary.
- CMS instructed its contractors to facilitate the processing of claims for services furnished by physicians to treat patients outside the normal settings (e.g., shelters).
- CMS paid the inpatient acute care rate and any cost outliers for Medicare patients that no longer needed acute level care but remained in a hospital located in the states with PHE areas until the patient could be moved to an appropriate facility.
- For those teaching hospitals that were training residents that were displaced by the hurricane, CMS temporarily adjusted the hospital's full-time equivalent cap on residents, as needed, to allow the hospital to receive indirect or direct graduate medical education payments for those displaced residents. The temporary adjustment applied as long as the original program in which the displaced resident trained, remained closed.
- Accelerated or advance payments were available to those providers who were still rendering some services or were taking steps to be able to furnish services again, despite having their practice or business affected or destroyed by the hurricane.
- CMS instructed its contractors to process immediately any requests for accelerated payments or increases in periodic interim payments for providers affected by the hurricane.
- Fiscal intermediaries were instructed to increase the rate of the accelerated payment to 100 percent and extend the repayment period to 180 days on a case-by-case basis.

<ul> <li>CMS instructed its intermediaries to approve requests for extensions to cost report filing deadlines for providers affected by the hurricane</li> </ul>
<ul> <li>Fiscal intermediaries were instructed to accept other data they determined were adequate to substantiate payment to the provider when a facility's records were destroyed. This determination was done on a case-by-case basis.</li> </ul>
<ul> <li>CMS allowed providers who waived the coinsurance and deductible amounts for indigent patients affected by the hurricane to claim bad debt, even in cases where documentation regarding a patient's indigence was unavailable. Providers were required to note their observations or submit any documentation they could along with a brief signed statement by medical personnel regarding the patient's indigence.</li> </ul>
"Medicare Extraordinary Circumstances" exception
Medicare provides for an "extraordinary circumstances" exception under capital PPS. Medicare's PPS includes payment for hospital inpatient capital costs on a per-discharge basis. The extraordinary circumstances exception provision provides an additional payment if a hospital incurs unanticipated capital expenditures in excess of \$5 million (net of proceeds from other funding sources, including insurance, litigation, and government funding such as FEMA aid) due to extraordinary circumstances beyond the hospital's control (e.g., a flood, fire, or earthquake). For most hospitals, the exception payments for extraordinary circumstances are based on 85 percent of Medicare's share of allowable capital costs (100 percent for sole-community hospitals) attributed to the extraordinary circumstance. The payments are made for the annualized portion of the extraordinary circumstance costs, over the useful lifetime of the assets, not in a lump sum.
Other Flexibilities
CMS permitted Medicare FFS contractors, through its FFS medical director staff, to disclose information from the claims history to providers for purposes of treating patients displaced by the hurricanes. The provider was authenticated, based on its provider number and information about the beneficiary the provider was treating. This process of releasing treatment history was particularly helpful in situations, e.g., where cancer patients presented and the patients were unable to communicate treatment history, particularly chemotherapy dosages.

Sanctions and penalties that would have arisen from non-compliance with certain provisions of the Health Insurance Portability and Accountability Act (HIPPA) privacy regulations, including requirements to obtain patients agreement to speak with family members or friends or to honor a patients request to opt out of the facility directory, were temporarily suspended as part of the PHE.