College of American Pathologists
325 Waukegan Road, Northfield, Illinois 60093-2750
800-323-4040 • http://www.cap.org

Advancing Excellence

Direct Response To:
DIVISION OF GOVERNMENT
AND PROFESSIONAL AFFAIRS
1350 I Street, NW, Suite 590
Washington, DC 20005-3305
202-354-7100 Fax: 202-354-7155
800-392-9994 • http://www.cap.org

October 25, 2007

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health & Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-2213-P
Medicaid Outpatient Hospital Service Definition

Dear. Mr. Weems:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the Notice of Proposed Rulemaking (NPRM) to amend the definition of outpatient hospital services for the Medicaid program. The nearly 16,000 pathologist members of the CAP represent board-certified pathologists and pathologists-in-training with a shared mission to advocate for high-quality and cost-effective medical care. To protect access by Medicaid beneficiaries to high quality laboratory services, the CAP asks CMS to include in the final rule a special provision for payment of clinical diagnostic laboratory services furnished for hospital outpatients, as described below.

The NPRM proposes an amendment to the definition of outpatient hospital services under the Medicaid program. The amendment will limit Medicaid coverage and payment for outpatient hospital services, including clinical diagnostic laboratory services, to facility services only. Clinical diagnostic laboratory services are defined broadly by certain State Medicaid Plans to include both clinical and anatomic pathology services.

The CAP is concerned that the proposed rule may result in non-coverage and, therefore, non-payment for certain pathology services. To protect against this unintended consequence, the CAP recommends a special provision to ensure that pathology services furnished for a hospital outpatient can continue to be reimbursed as an outpatient hospital service in accordance with the relevant State Medicaid Plan fee schedule.

The stated intent of the amendment is to more closely align certain payment categories under the applicable upper payment limits for outpatient hospital services in accordance

disruption to the delivery of essential medical services to Medicaid beneficiaries. Any questions regarding the CAP comments should be directed to Donna Meyer, in the CAP Division of Membership and Advocacy, at 202-354-7112 or dmeyer@cap.org.

Sincerely,

Jared N. Schwartz MD PhD FCAP

Jared N. Schwartz MD, PhD, FCAP
President

CALIFORNIA

children's

HOSPITAL

ASSOCIATION

1215 K STREET SUITE 1930
SACRAMENTO, CA 95814
T 916.552.7111
F 916.552.7119
www.ccha.org

October 26, 2007

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Attn: CMS-2213-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Attn: CMS—2213--P
Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit

Dear Sir/Madam:

On behalf of the children in California served by the Medicaid program, the California Children's Hospital Association (CCHA) appreciates the opportunity to submit comments to the Centers for Medicare and Medicaid Services (CMS) on its proposed rule on Medicaid outpatient hospital services published in the September 28th *Federal Register.* CCHA represents eight non-profit children's hospitals in the State. California's children's hospitals are major providers of outpatient services for children insured by Medicaid. The proposed regulatory changes could have a negative impact on our hospitals and the children we serve. Thus, we urge CMS not to implement the proposed rule.

In May 2007, Congress passed a one-year moratorium that halted CMS from implementing changes to state financing mechanisms and graduate medical education payments under Medicaid. This moratorium denies CMS the authority to implement the rule as currently drafted. The National Association of Public Hospitals completed a detailed legal analysis of this proposed regulation and has found that it violates the current moratorium in two ways: 1) the proposed regulation includes language from the state financing mechanism regulation that redefines categories of providers for the purposes of the upper payment limits (UPLs); and, 2) the proposed regulation would no longer allow graduate medical education costs in the calculation of the outpatient UPL.

Additionally, the issues listed below are of further concern to us:

The Proposed Rule Overlooks Critical Outpatient Hospital Services for Children
We understand CMS's interest in providing more clarity on what is and what is not a Medicaid outpatient hospital service. However, the narrow Medicare definition that CMS is suggesting be used in the proposed regulation does not reflect the population served by the Medicaid program. More than one-fourth of all children are insured by Medicaid and over 50 percent of Medicaid beneficiaries are children.

The Medicare definition for outpatient services is inappropriate for children because it was not developed to address their unique health care needs, and the services they require. Services not specified in the Medicare definition include, but are not limited to, dental and vision services, annual checkups, and immunizations. The different health care needs of children and adults should be examined, and changes should be made before the Medicare definition is adopted for the Medicaid population. If this is not done, important outpatient health care services for children could be threatened.

The Proposed Rule Threatens the Financial Viability of Children's Hospitals

Children's hospitals are major providers of outpatient hospital services for children. Collectively, the children's hospitals in California provide more than 1.5 million outpatient visits each year. In addition, on average, children insured by Medicaid account for more than 55 percent of all outpatient visits. The children's hospitals in California currently provide a full range of outpatient services to children insured by Medicaid.

We recognize that the regulation says that services taken out of the outpatient hospital services definition could still be provided under different benefit categories. However, by removing critical services provided to children out of the definition, CMS would be lowering reimbursement for these important services that the hospitals provide to children insured by Medicaid. This possible payment reduction would exacerbate the inadequate Medicaid outpatient reimbursement the children's hospitals in California receive, which already falls substantially below the cost of care we provide.

The proposed regulation would also exclude services provided by entities that do not fall under the strict definition of provider-based departments of a hospital. This new requirement could jeopardize the outpatient care provided in some of our outpatient clinics that, due to the fragile health of many of our patients, are dependent upon the hospitals and should be reimbursed accordingly. If the services provided in our clinics or other outpatient sites would no longer be reimbursed at the outpatient hospital services level than that would affect our ability to provide these services in the community.

The proposed regulation may also affect the calculation of our Medicaid Disproportionate Share Hospital (DSH) payments. If services are no longer classified as outpatient hospital services, then they would no longer be included in the calculation of our DSH cap. This could result in smaller DSH payments vital to California's safety-net hospitals, including children's hospitals. Similarly, changes to Medicaid graduate medical education (GME) payments would have a negative impact on the hospitals – including children's hospitals – that serve low-income Californians while training the State's future physicians.

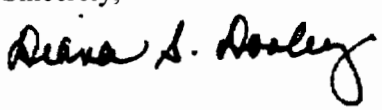
CMS Is Unable to Estimate Impact of the Proposed Rule

Due to a lack of data, CMS says it is unable to estimate the impact of the proposed regulation. Before a regulation of this magnitude is implemented, the impact should be specified and addressed. Additionally, CMS does not address the potential effect on children enrolled in the program or their providers in adopting a Medicare service definition. This change could reduce the services hospitals are able to provide for children and, therefore, diminish children's access to outpatient hospital services.

Conclusion

We encourage CMS to delay the implementation of the regulation to allow time for a thorough review of the proposed regulation's impact on children enrolled in Medicaid and the providers who serve them. We appreciate the opportunity to present our comments. Please contact me should you require additional information.

Sincerely,



Diana S. Dooley
President & CEO

cc: Board of Directors

SOUTH CAMERON MEMORIAL HOSPITAL SYSTEMS
5360 W. Creole Hwy
Cameron, Louisiana 70631
(337)542-5411 Main (337)542-4110 Fax

October 24, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2213-P
Mail Stop C4-26-05,
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-2213-P--Outpatient clinic and hospital services facility services definition

Dear Secretary Leavitt:

Thank you for the opportunity to comment on CMS' 2213-P- Outpatient clinic and hospital services facility services definition proposed rule that was published in the Federal Register on September 28, 2007.

On behalf of South Cameron Memorial Hospital, I am writing to object to the outpatient clinic and hospital services facility services definition proposed rule.

We are a small rural hospital located in Cameron, Louisiana, with a hospital-based rural health clinic (RHC) that functions as part of the hospital. The hospital-based RHC helps the hospital provide the same care previously provided by the emergency department, but in a more clinically appropriate and less costly setting. The proposed rule would cover more expensive uncompensated emergency room care, but uncompensated hospital-based RHC care would not be included in DSH (disproportionate share hospital) eligible costs. By establishing hospital-based RHCs, our hospital has attempted to end the burden placed on emergency rooms that are used for primary care. Now, CMS is attempting to reestablish the use of the emergency department for routine medical care by those who are unable to afford other forms of care. This is not appropriate. Use of hospital-based RHC's should be encouraged, not discouraged, because RHC use will save taxpayer dollars.

Our hospital-based RHC functions as part of the hospital: therefore, the hospital employs the RHC's personnel, maintains payroll, pays all overhead expenses, owns or leases the RHC building, provides medical supplies and credentials the physicians and physician assistants. The RHC is a vital component of the hospital as it assists the hospital with providing access to quality primary care services.

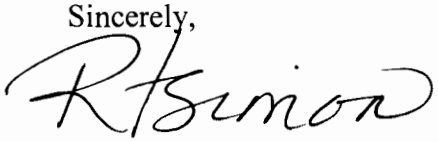
Under this proposal, the costs of the RHC would be excluded from "outpatient costs" of the hospital for DSH calculation purposes. It is imperative that CMS is cognizant to that fact that excluding the hospital-based RHC from the eligible costs will have an adverse effect on our hospital's ability to provide services at the RHC. As aforementioned, the majority of the overhead expense to operate the RHC, is provided by the hospital using the DSH funding. If the rule is implemented, our hospital will lose hundreds of thousands of dollars per year in DSH funding. Excluding the hospital-based RHC from DSH funding will limit our ability to provide care to those who live in poverty stricken areas and are in need of health care services.

CMS' efforts to exclude hospital-based RHC's costs in disproportionate share calculations would impede care and will be a detriment to access to primary care in rural communities. This alone is contrary to good public policy. Rather than reward use of cheaper and more appropriate RHC services, the proposed rule does just the opposite. The rule actually creates financial incentives to use scarce and expensive emergency department services, even though hospital-based RHC services can be provided at a fraction of the cost and do not tie up critical emergency care resources.

Due to these concerns, I respectively ask that you withdraw the proposed rule you refer to as CMS-2213-P--Outpatient clinic and hospital services facility services definition.

Thank you for considering these comments.

Sincerely,



Rita T. Simon RN,BSN,CLNC
Chief Executive Officer
South Cameron Memorial Hospital Systems

BEFORE THE
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Matter of	)
	)
Proposed Medicaid Program Rules on	)
	)
OUTPATIENT HOSPITAL AND CLINIC SERVICES	)
	)
CMS 2213-P	)
	)

JOINT COMMENTS OF FIFTEEN STATES AND STATE MEDICAID AGENCIES

These comments are submitted on behalf of the agencies and officials responsible for administering the Medicaid program in the States of Alaska, Connecticut, Illinois, Maryland, Michigan, Missouri, New Jersey, Oklahoma, Pennsylvania, South Dakota, Tennessee, Utah, Vermont, Washington and Wisconsin ("Commenting States") in response to the proposed rule amending the definition of outpatient hospital services in the Medicaid regulations. 72 Fed. Reg. 55158 (Sept. 28, 2007). The deadline for comment imposed by the Centers for Medicare & Medicaid Services (CMS) is plainly inadequate for a rule that, if finalized, would have far-reaching and significantly burdensome effects on State Medicaid programs. Moreover, in the limited time the Commenting States have had to review the proposed rule, it has become clear that CMS's proposed amendments to the outpatient hospital services definition and the upper payment limit (UPL) are misguided.

I. CMS should have allowed at least a 60-day comment period

Provision of rule commented upon: The proposed rule was published in the Federal Register on September 28, 2007, and the deadline for comment is October 29, 2007 – the first business day following a 30-day period starting on the date of publication. 72 Fed. Reg. at

55158. CMS states that "[t]he provisions proposed in this regulation address completely different policy matters than those set forth in CMS–2258–FC," which is subject to a congressionally imposed moratorium. *Id.* at 55160. CMS further states that the proposed rule "does not impose information collection and recordkeeping requirements." *Id.* at 55164. CMS claims that its proposed rule "would not significantly alter current practices in most States," that the rule will not have "significant economic effects," and that only one State "could be affected by this rule." *Id.* at 55164-65. Finally, CMS states that the proposed rule will not have significant effects within the meaning of Executive Order 12866, the Regulatory Flexibility Act, section 1102(b) of the Social Security Act ("Act"), the Unfunded Mandates Reform Act, or Executive Order 13132. *Id.* at 55165.

A 30-day comment period is plainly inadequate: The proposed rule, if finalized, threatens to affect State Medicaid programs in major ways. At the very least, the rule will impose substantial new administrative burdens on all States. A comment period of at least 60 days should have been allowed.

First, CMS ignored the mandatory 60-day notice and comment requirement of the Paperwork Reduction Act. CMS's conclusory assertion that its proposed rule does not impose information collection and recordkeeping requirements is undercut by the proposed rule itself. The revisions to the UPL regulation alone create major new information collection requirements involving hospital and clinic cost reports and Medicare fee schedules. The proposed rule plainly "concern[s] [a] proposed collection of information" within the meaning of the Paperwork Reduction Act, 44 U.S.C. § 3506(c)(2)(A); *id.* § 3502(3)(A), and warrants a mandatory 60-day notice and comment period, *id.* § 3506(c)(2)(A).

CMS also should have permitted a 60-day comment period under other authorities. A comment period of at least 60 days is the default under Executive Order 12866, § 6(a)(1) (Sept. 30, 1993), *Regulatory Planning and Review*, *as amended by* Exec. Orders 13258 (Feb. 26, 2002) and 13422 (Jan. 18, 2007) (providing that "each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days"). Given the wide-ranging application and substantial administrative burdens of the proposed rule, it was improper for CMS to provide for a comment period only *half* as long as the period proper for *any* proposed regulation.

Any change to the definition of outpatient hospital services will plainly apply to each and every State, not just the one unnamed State mentioned by CMS. And any change to the manner in which the UPL must be calculated for hospital outpatient services and clinics will also apply to each and every State. These changes are far from minor. The UPL methodology proposed by CMS, especially with respect to clinics, is immensely complex. It would require States to obtain, process, and provide to CMS information that is orders of magnitude more complicated and detailed than what is required under the current regime.

The proposed rule cannot seriously be characterized as anything other than major. It is "significant" within the meaning of numerous authorities, such as Executive Order 12866 § 3(f) (defining "significant regulatory action" as "any regulatory action that is likely to result in a regulation that may . . . adversely affect in a material way . . . a sector of the economy, . . . public health or safety, or State, local, or tribal governments or communities" or that may "[r]aise novel legal or policy issues arising out of legal mandates"); the Regulatory Flexibility Act; section 1102(b) of the Social Security Act; the Unfunded Mandates Reform Act of 1995; Executive Order 13132; and the Administrative Procedure Act, 5 U.S.C. §§ 801, 804(2).

That CMS permitted a comment period of only 30 days indicates either that CMS does not understand the scope of its own proposed rule or that CMS hopes States will fail to realize the full effects of the rule until it is too late for them to comment on it. Neither possibility is acceptable. The proposed rule is complicated and important, and States and other affected entities should be given more time to understand how they might be affected and to comment.

II. The proposed rule is misguided in a number of respects.

Given the short period of time provided to assess and comment upon the rule, the Commenting States briefly describe the following concerns that have so far been identified:

A. The Proposal Would Prohibit the Use of All-Inclusive Rates. Despite the flexibility given to States in the Social Security Act in defining the scope of services and in setting reimbursement rates, the proposed rule would appear to invalidate the long-accepted practice, followed in some States, of paying all-inclusive rates for outpatient hospital services. The all-inclusive rate is paid to the hospital and includes a professional service component. Under such a system, the physician cannot bill Medicaid separately. States frequently use the all-inclusive rate as a means of controlling costs.

By excluding professional services from the definition of outpatient hospital services, the new rule would apparently prohibit all-inclusive rates and require States to pay physicians and other professionals separately from the facility, requiring amendments to long-standing state reimbursement methodologies. The proposed rule does not point to any statutory reason or public policy that would support that position. Both are mandatory services under Section 1905(a) of the Social Security Act and nothing in the Act requires that they be separately reimbursed.

B. The importation of the Medicare definition of outpatient services into Medicaid is inappropriate. The Medicare definition of outpatient services is targeted to the elderly and disabled who are enrolled in that program. By contrast, Medicaid targets younger, broader, and more vulnerable patients who face barriers to access to care and are therefore more likely than Medicare patients to use a hospital in their community as their "medical home." The Medicare definition of outpatient services is too narrow and does not appear to include services that in many States have traditionally covered as outpatient hospital services for the Medicaid population, including dental and vision services and some types of preventive care. Because of the difference in the patient base, application of the Medicare definition of outpatient service will have a particular adverse impact on children's hospitals.

C. The proposed rule penalizes hospitals that seek to serve people in their communities by excluding services provided in outpatient clinics that are not departments of the hospitals. In order to deter inappropriate use of expensive hospital emergency room services and to better serve their patients, many hospitals have established outpatient clinics, and receive support for those services through Medicaid outpatient hospital reimbursement or disproportionate share hospital payments for the costs of serving the low-income uninsured. To the extent that the new rule was intended to shut off that type of reimbursement, it reflects spectacularly poor public policy that reduces the ability of hospitals to reach out and serve patients in less expensive, more convenient, and more clinically appropriate settings.

D. The UPL calculation for outpatient hospital services improperly excludes graduate medical education (GME) costs, in violation of congressional mandate. On May 25, 2007, as part of the US Troop Readiness, Veterans Care, Katrina Recovery, and Iraq Appropriations Act of 2007, Congress prohibited the Secretary of Health and Human Services

from taking "any action" to "finalize or otherwise implement" any regulation prohibiting Medicaid reimbursement for GME costs. The cost-to-charge and payment-to-charge ratios in the proposed rule are defined to exclude GME costs. Accordingly, the proposed UPL is in violation of the congressional mandate.

E. The UPL calculation for clinic services is extremely burdensome and complex, and its application may result in Medicaid rates that cannot assure access to services. Currently, there are a number of States that do not regularly conduct UPL calculations for clinic services or have used cost as a proxy for the UPL. The proposed rule no longer permits that approach but instead would require States to calculate a clinic UPL by making a comparison on a procedure-by-procedure basis to the amount Medicare pays for equivalent services. This entails pulling information from thousands of lines on Medicare's detailed fee schedules, and by making additional complex adjustments to these numbers to remove components that CMS contends are not reimbursable as clinic services under Medicaid.

Clinics are important service providers in the Medicaid program, and for that reason many are reimbursed at or near cost, similar to the federally-imposed requirement for federally-qualified health centers and rural health clinics. To the extent that Medicare reimbursement is less than costs, the proposed UPL calculations could lead to a reduction in Medicaid payments to these important providers.

F. The rule implicates the moratorium on CMS's implementation of the Cost Limit for Providers Operated by Units of Government. On January 18, 2007, CMS published its proposed regulation on Cost Limits for Providers Operated by Units of Government, 72 Fed. Reg. 2236. On May 25, 2007, as part of the US Troop Readiness, Veterans Care, Katrina Recovery, and Iraq Appropriations Act of 2007, Congress prohibited the Secretary of Health and

Human Services from taking "any action" to "finalize or otherwise implement" the regulation proposed on January 18, 2007. Pub. L. No. 110-28, § 7002 (2007). Four days after that instruction, the final rule was published in the Federal Register, with a purported effective date of July 30, 2007.

Although CMS has stated its intent to comply with the moratorium provision, it is apparent that the current proposal will significantly affect reimbursement to hospitals and clinics of all types, including those operated by units of government. CMS–2258–FC, which is subject to a moratorium, purports, among other things, to "clarif[y] the documentation required to support a Medicaid certified public expenditure" and to "limit[] Medicaid reimbursement for health care providers that are operated by units of government to an amount that does not exceed the health care provider's cost of providing services to Medicaid individuals." 72 Fed. Reg. 29748, 29748 (May 29, 2007). The proposed rule would alter the definition of outpatient hospital services, thereby altering the costs and expenditures that CMS would deem acceptable under CMS–2258–FC. Thus, CMS's claim that the proposed rule concerns matters different from those addressed in CMS–2258–FC is patently incorrect.

III. Conclusion

For the reasons discussed above, the Commenting States urge CMS to withdraw the proposed rule. Should CMS insist upon proceeding with the proposed rule, the Commenting States urge CMS to reissue the proposed rule with at least a 60-day comment period, and to substantially modify its proposal in accordance with the foregoing comments.

Respectfully submitted,

Caroline M. Brown
Leah Pogoriler
Covington & Burling LLP
1201 Pennsylvania Ave, N.W.
Washington, D.C. 20004-2401
(202) 662-6000

Attorneys for the Commenting States

October 29, 2007

STATE OF NEW YORK
DEPARTMENT OF HEALTH

Corning Tower The Governor Nelson A. Rockefeller Empire State Plaza Albany, New York 12237

Richard F. Daines, M.D.
Commissioner

Wendy E. Saunders
Chief of Staff

October 29, 2007

Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD. 21244-1850

Re: CMS-2213-P
Comments on Proposed Rule Medicaid Program;
Clarification of Outpatient Clinic and Hospital
Facility Services Definition and Upper Payment
Limit (UPL)

Dear Administrator Weems:

The New York State Department of Health respectfully submits this comment letter on the proposed rule amending the regulatory definition of outpatient hospital services for the Medicaid program published in the September 28, 2007 Federal Register (72 Federal Register 55158) for the Centers for Medicare and Medicaid Services.

The Department opposes implementation of this proposed rule because it violates provisions of the moratorium contained in the US Troop Readiness, Veterans Care, Katrina Recovery, and Iraq Appropriations Act of 2007 (Moratorium), narrows the regulatory definition of outpatient hospital services, and adopts restrictive and mandatory approaches to calculating upper payment limits for outpatient hospital and clinic services provided by private providers.

Justification for Opposition to Proposed Rule

In the opinion of the Department, the proposed rule violates provisions of the statutory Moratorium contained in the Iraq Accountability Appropriations Act of 2007 in at least two ways. First, and of much significance to New York, the proposed rule effectively precludes states from including Graduate Medical Education (GME) costs in the outpatient UPL, thus, limiting the State's flexibility to support GME, which is in direct violation of the Moratorium. The language of the Moratorium clearly prohibits CMS from taking any action through promulgation of regulation, issuance of regulatory guidance, or other administrative action that restricts payments for GME under the Medicaid program. The detailed new requirements

contained in the proposed rule for calculating cost for purposes of the outpatient hospital UPL reduces the ability of states to make payments for GME by excluding GME costs from those that may be included. The Department would like to reiterate the comments to Proposed Rule CMS-2279-P, Medicaid Program, Graduate Medical Education, submitted to CMS in its letter dated June 21, 2007. This proposed rule overturns the federal government's historical commitment to share in the Medicaid program's support to train physicians that serve America's hospitals and care for all patients including low-income families, the elderly, and persons with disabilities. New York supports over 16,000 residents, on an annual basis, at approximately 100 teaching hospitals through the state. A critical component of this training process is provided in the ambulatory setting.

Second, in the proposed rule, CMS has issued regulatory language similar to the final Medicaid Cost Limit Rule that redefines the categories of providers (state, non-state government and private) subject to UPLs. This proposed change removes all reference to facility ownership from consideration in applying the outpatient UPL, which is clearly within the scope of the prohibition adopted by Congress in the Moratorium.

The proposed rule also includes significant changes to the federal regulatory definition of outpatient hospital services, adopts restrictive and mandatory approaches to calculating the UPLs for outpatient hospital and clinic services provided by private providers, and has an indirect impact on disproportionate share hospital (DSH) reimbursement.

CMS states that it is necessary to limit the scope of outpatient hospital services under the Medicaid program in order to more accurately meet the requirements of the upper payment limit rule. However, not only does the law not require this, but CMS is attempting to "put the cart before the horse". CMS' proposal would narrow the definition of "medical assistance", long-standing statutory language that is at the core of the Medicaid statute, in order to accommodate a more recent regulation that CMS itself created. The Medicaid statute allows coverage of outpatient hospital services with no definition that restricts the scope of these services (Social Security Act §1905(a)(2)). CMS itself has recognized the broad scope of these services with the current regulation's definition of outpatient hospital services. By contrast, the UPL rule exists only in regulation. There is no express language in the Social Security Act imposing a Medicare-based ceiling on Medicaid payments. As CMS admits in the preamble, the UPL rule is based only on CMS' interpretation of legislative history. (72 Fed. Reg. 55159-55160). An administrative agency cannot adopt a regulation that is contrary to statute, and CMS cannot alter the Social Security Act by regulation especially when the alteration would narrow long-standing statutory language central to the law's scheme just to accommodate another CMS regulation.

CMS also states that the rule is necessary to avoid the possibility of services being covered by more than one category under a state's Medicaid program. However, there is nothing in federal Medicaid law that prohibits the same service from being classified into more than one funding option. In fact, many services can be paid under different categories of a state's Medicaid program. To cite just a few examples of this overlap, doctor's visits can be paid as physician's services or clinic services, and physical therapy can be paid for as part of an all-inclusive rate for intermediate care facilities for the mentally retarded (ICF/MR), as separately billed therapy, or as a clinic visit.

The narrowing of the scope of Medicaid outpatient hospital services to match those reimbursed by Medicare severely limits the State's flexibility to design and implement Medicaid reimbursement methodologies other than one similar to Medicare and represents a significant change. New York has many all-inclusive reimbursement methodologies under its Medicaid program, and this proposed rule would require significant State statutory and regulatory actions and modifications to the State's Medicaid Plan. In addition, this proposal may actually result in higher Medicaid expenditures since some all-inclusive methodologies, which may be limited by cost ceilings, include physician services. The proposed rule would require these services to be unbundled and paid for separately, quite possibly resulting in higher aggregate Medicaid payments across all providers.

Additionally, for physician services rendered to Medicare beneficiaries, 42 CFR §415.160 allows a teaching hospital to elect to receive payment on a reasonable cost basis for the direct medical and surgical services of its physicians in lieu of fee schedule payments that might otherwise be made for these services. For those hospitals that meet the qualifications and are approved by the fiscal intermediary for this election, physician services rendered to Medicare beneficiaries for hospital inpatient and outpatient services are paid via bi-weekly lump sum payments that are reconciled to actual reasonable costs as reported in the annual Medicare cost report (CMS-2552). There is no fee billing for physician services for these hospitals. Currently in New York, there are sixteen (16) mental health facilities that have been approved for this payment option. The proposed rule is in direct conflict with this approved Medicare payment methodology.

Although CMS does not discuss the effect on hospital DSH payments, the State believes the redefining of allowable outpatient hospital services will also impact these payments. Federal statute and regulation require that DSH payments can be paid to the extent that the State has included only costs incurred for inpatient hospital and outpatient hospital services in the estimate of Medicaid and uninsured losses for each DSH hospital. To the extent that some of the costs that have been historically included and allowed in the DSH calculations, especially physician services, are now deemed to not be classified as related to outpatient hospital services, additional financial burdens will be incurred as a result of reduced DSH payments. The State believes that any attempt to reduce Federal Financial Participation under DSH as a result of this interpretation would require statute and regulation specific to this issue and cannot be enforced through this regulation.

CMS is also proposing restrictive and mandatory approaches to the calculation of UPL's for outpatient hospital and clinic services. First, CMS is proposing that the outpatient hospital UPL calculation only include services that meet the new definition of outpatient hospital services and also appear on outpatient-specific Medicare cost report worksheets. Second, CMS proposes to limit the State's calculation of the hospital outpatient UPL to one of two permissible methodologies, Medicare allowable costs or allowable payments, both of which are based on ratios from designated sections of the Medicare cost report. These specific worksheets of the Medicare cost report explicitly exclude costs related to GME. As previously stated, this violates the provisions of the Moratorium.

In addition, the proposed rule's prescriptive UPL methodology does not recognize or address the unique situation of all-inclusive rate (flat-rate) providers. Historically, CMS has recognized the uniqueness of this category of providers by making separate provisions for cost apportionment in the Medicare cost report where a provider does not maintain departmental charges for the apportionment of cost. The "flat-rate" hospitals have been allowed to complete their Medicare cost reports by using statistics to allocate costs instead of using the cost-to-charge methodology. The rationale for this exception is that use of a cost-to-charge ratio does not make sense where the charge structure is not consistently maintained. A payment-to-charge ratio would be similarly distorted. The prescriptive nature of the proposed rule does not appear to allow any flexibility for an exception where Medicare has allowed an exception from the use of charge information in the annual cost report. At the very minimum, an exception should be allowed.

Also, the proposed rule would require the State to calculate a UPL for clinic services either by adopting reimbursement methodologies that pay a specified percentage, not greater than 100% of the Medicare rate, or by demonstrating that in the aggregate, Medicaid fee schedule rates are less than what Medicare would pay based on a comparison by CPT code to the amount Medicare pays for equivalent services. This is a significant change of policy by CMS since a cost-based methodology, based on cost to charge ratios has been approved in the past. In addition, the State utilizes a cost-based rate methodology subject to ceilings for clinics. Since Medicare payment rates are usually much lower than cost, these mandated approaches may result in an adverse financial impact to some providers.

In addition, the crosswalk that would be required to Medicare fee schedules or CPT codes ignores the fact that New York's Medicaid program funds clinics that provide habilitation and other services to persons with developmental disabilities. This funding arrangement is in accordance with current law and New York's Medicaid State Plan, as currently approved by CMS. There is no Medicare fee schedule or CPT code for many of the services provided in these clinics. It would be impossible for the State to perform the UPL calculation the rule would require for these clinics. The proposed rules recognizes that a Medicare crosswalk is not feasible for dental services because there is no Medicare coverage for dental services, but does not make a similar exception for other services needed by persons with developmental disabilities.

Finally, the State disagrees with CMS that this proposed rule should not be considered a major rule under the Congressional Review Act. The proposed regulatory changes are major policy changes that will require significant changes to the State's reimbursement methodologies, UPL calculations, and Medicaid State Plan; will require state statutory and regulatory actions; and may result in reduced DSH payments. The resulting fiscal impact to the State's hospital and clinic provider community may be significant. CMS, in Section VI of the preamble to the proposed rule, states, "Due to the lack of available data, we cannot determine the fiscal impact of this proposed rule." Yet, CMS makes the statement that because the changes will not result in a significant financial impact, the proposed rule is not considered a major rule and thus only requires a 30-day comment period. The State contends that CMS is making contradictory statements and this proposed rule should be considered a major rule. CMS also asserts that this rule is only a clarification of existing Federal rules, but the State believes that the proposed rule

in fact represents a fundamental change to existing Federal regulatory authority, and as such, cannot be applied retroactively.

In conclusion, the State strongly opposes the proposed rule and urges CMS to reconsider the issuance of a final rule that restricts the State's flexibility to manage its Medicaid program, eliminates Medicaid funding for GME, requires significant administrative action by the State, reduces DSH payments to hospitals, and may have a significant adverse financial impact to our provider community. Should CMS wish to discuss the impact of this proposal to New York State in further detail, please contact my office at (518) 474-3018.

Sincerely,

Deborah Bachrach
Medicaid Director
Deputy Commissioner
Office of Health Insurance Programs

18

Hayes, Yolanda K. (CMS/OSORA)

Subject: Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit

Dear Mr. Weems:

The National Association of State Mental Health Program Directors (NASMHPD) is writing to request clarification on the Notice of Proposed Rulemaking (NPRM) to amend the regulatory definition of outpatient hospital services for the Medicaid program published in the Federal Register on September 28.

NASMHPD represents the $27.3 billion public mental health service delivery systems serving 6.1 million people annually in all 50 states, four territories, and the District of Columbia. It is the only national association to represent state mental health commissioners/directors and their agencies. In addition, NASMHPD has an affiliation with the approximately 220 state psychiatric hospitals. Our members administer and manage community-based systems of care for the millions of individuals with serious mental illness who at times require immediate access to a variety of inpatient facilities and psychiatric units in general hospitals but are often cared for successfully on an outpatient basis.

Since this regulation could have a significant impact on the provision of services in state psychiatric hospitals for patients over 64 and could have implications for the public system at large, we respectfully request additional clarification of the ruleâ€™s intent. We are especially concerned about the impact on the provision of rehabilitation services in outpatient settings. NASMHPD is committed to the goals laid out in the Presidentâ€™s New Freedom Commission on Mental Health which focused on recovery for all individuals with mental illnesses. Changes in the Medicaid program that threaten progress toward that goal are of great concern to us.

Unless the intent of the rule is clarified and its impact assessed, we request that the rule be withdrawn.

Sincerely yours,
Elizabeth Prewitt

Director, Government Relations
National Association of State Mental Health
Program Directors
66 Canal Center Plaza
Ste. 302
Alexandria, VA 22314

CALDWELL Memorial Hospital

October 21, 2007

Centers for Medicare and Medicaid Services (CMS)
Department of Health and Human Services
Attention: CMS-2213-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: CMS-2213-P Clarification of Outpatient Clinic & Hospital Facility Services Definition and Upper Payment Limit.

Dear CMS:

The purpose of this letter is to urge CMS to eliminate the provisions of proposed rule file code CMS-2213-P regarding outpatient clinic and hospital services facility services definition that was published in the Federal Register on September 28, 2007. This proposed rule will limit rural health care availability while simultaneously increasing ER costs to facilities, taxpayers and, in turn, the government. The proposed rule asserts that it is trying to align Medicare and Medicaid payments, but in reality, will end up pushing them further apart effectively paying significantly less for Medicaid services in already under-paid rural health settings. Additionally, the proposed rule, CMS-2213-P, does NOT support the *Medical Home Model for the Uninsured* that Secretary Leavitt endorsed for our state and it will not be feasible under this ruling.

We are a small rural hospital located in Columbia, Louisiana, with three hospital-based rural health clinic's (RHC) that fully function as part of our hospital. The hospital employs all of the RHC personnel, pays all the expenses of the RHC, performs quality assurance responsibilities, and credentials the physicians and mid-level practitioners employed by the RHC. The hospital owns the building in which the RHC is located, handles payroll functions for the RHC, and provides medical supplies to the RHC. Yet, under the proposed rule, the costs of the RHC would be excluded from "outpatient costs" of the hospital for disproportionate share calculation purposes. This proposed rule, CMS-2313-P, will have a catastrophic effect on rural healthcare and the availability of services to those who need care the most--- the poor and the indigent.

This proposal *will* limit our hospital's ability to provide services at the RHC's, because disproportionate share funding covers much of the cost of the RHC services. Nothing has changed to give the uninsured and indigent population more income to afford healthcare elsewhere, so now not only can they not afford healthcare, there will very few places, if any, for them to receive healthcare. It is the rural population as a whole that will suffer by this outpatient definition excluding RHC.

Our area, like the rest of the state, faces a severe problem with emergency room use by patients who actually only need clinic services. Because they can be seen in the emergency department (eventually), patients with no insurance traditionally have used the emergency department like a primary care clinic. Such improper use of the emergency department by indigent patients strains our hospital's limited resources. It also makes it difficult for those patients to get timely, preventative care.

Our hospital-based RHC solved this problem by giving those patients a less expensive and readily-available alternative to the emergency room (ER). This has allowed us to meet their needs in a timely manner and at a **much lower cost**. It also allowed us to provide better emergency services, because we no longer faced the burden of providing expensive primary care through the emergency department. It is certain that there will be an increase in unnecessary ER visits that would have been avoided if the patient has a clinic to access.

In short, CMS' effort to exclude our hospital-based RHC's costs in disproportionate share calculations is a bad idea because it removes much needed monetary support for the RHC's hospital-based clinic services. This will mean an increased inappropriate burden on our emergency department. It will also mean that many who need care simply will not get it.

The rule also asserts that it is trying to more closely align Medicare and Medicaid payments. Congressional intent was to let each State set rates that were efficient and economical. They have done this and it is successful in our state. **Under the current status, the disproportionate share funding payments align our Medicaid and indigent costs more closely with our Medicare costs. If you take away our ability to receive this funding, then there will be a severe payment gap unless some restructuring of the outpatient payment rates occurs simultaneously with this proposed ruling.** Medicare and Medicaid could effectively be aligned in a provider-based RHC by increasing the encounter fees paid for Medicaid and Indigent patients to match the higher costs we are paid for Medicare encounters. Under that rationale, it would be very costly and unnecessarily harmful to input severe changes when we know the whole healthcare system in the United States will be restructured within a few years. For these reasons, the status quo and current outpatient clinic and hospital services definition should remain because it already achieves what CMS claims this proposed rule is set up to accomplish.

The Commonwealth of Massachusetts
Executive Office of Health and Human Services
Office of Medicaid
One Ashburton Place
Boston, MA 02108

DEVAL L. PATRICK
Governor

TIMOTHY P. MURRAY
Lieutenant Governor

JUDYANN BIGBY, M.D.
Secretary

THOMAS R. DEHNER
Medicaid Director

October 29, 2007

Kerry Weems
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2213-P
P. O. Box 8016
Baltimore, MD 21244-8016

Re: CMS 2213-P: Comments on Proposed Rule Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit

Dear Mr. Weems:

The Commonwealth of Massachusetts appreciates the opportunity to submit comments on the Proposed Rule regarding the Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit. Massachusetts would first like to express its support for the comments submitted by the National Association of Public Hospitals and Health Systems. Massachusetts also has a number of serious concerns about the impact of the proposed rule.

Moratorium: As a preliminary matter, we question CMS' authority to issue this NPRM given the Congressional moratorium[1] on rulemaking relating to proposed CMS regulations concerning Medicaid financing and governmental provider payment[2] ("Medicaid financing NPRM"), and graduate medical education[3] ("GME NPRM"). The provisions in this NPRM relating to upper payment limit calculations for private outpatient hospital and clinic services are inextricably linked to the proposed CMS regulations that are subject to the moratorium. Although the preamble indicates that CMS views the instant rulemaking as addressing "completely different policy matters" than those addressed in the Medicaid financing NPRM, the proposed outpatient hospital and clinic UPL regulation repromulgates 42 CFR 447.321 and cannot be implemented without reference to 42 CFR 433.50, both of which regulations are subject to the moratorium. Also, where CMS would appear to prohibit states from including graduate medical education (GME) costs in a cost-to-charge outpatient hospital upper payment limit calculation, the NPRM appears to violate the prohibition against restricting

[1] U.S. Troop Readiness Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, Pub. L. No. 110-28, Section 7002(a).
[2] 72 Fed. Reg. 29748 (May 29, 2007)
[3] 72 Fed. Reg. 28930 (May 23, 2007)

payments for GME under the Medicaid program. CMS should withdraw this NPRM on this basis.

Effective Date: This NPRM could require major administrative and operational changes for any state whose current outpatient hospital payment method bundles payments to a greater degree than the bundling in Medicare's OPPS. It could be difficult, if not impossible, to segregate from the upper payment calculation any service whose Medicaid payment is bundled into a state's approved outpatient hospital payment methodology, but is not included in Medicare's OPPS. This could require restructuring current approved Medicaid payment methodologies, issuing amendments to state regulations, provider agreements, and State Plans, and recalculating upper payment limits. If this regulation becomes final, states should be given sufficient time to implement these major changes.

The regulation, if finalized, should also provide states sufficient time to make any future administrative and operational changes that may be needed as a result of future changes in Medicare outpatient hospital coverage policies or payment methods.

Direct Comparison from Medicaid to Medicare: We have serious concerns about the proposed rule's assertion that "the scope of outpatient hospital services as defined by Medicaid would be the same as those included in the outpatient hospital UPL." Medicare and Medicaid are fundamentally different programs with different purposes, populations, and covered services. As such, we believe it is in direct conflict with Congressional intent to limit services that can be reimbursed under the Medicaid outpatient services provision of the SSA to those that are reimbursed under the Medicare OPPS. Congress established two separate programs and did *not* go so far as to equate Medicaid services to Medicare services.

CMS proposes to draw a bright line between services provided by outpatient hospitals and services within the scope of other State Plan service categories. However, the preamble, the proposed rule and existing Medicare OPPS provisions as well as Medicaid regulations governing State Plan provisions for other service categories do not bear out such a precise parsing of services. CMS' attempt to distinguish OPPS services from other State Plan services creates ambiguity for states and internal inconsistencies in this proposed regulation. Also, the preamble indicates that the following are within the scope of services that may be reimbursed as Medicaid outpatient hospital services: "prosthetic devices, prosthetics, supplies, and orthotic devices, durable medical equipment, and clinical diagnostic laboratory services." However, prosthetic services and durable medical equipment are separate Medicaid State Plan service categories. Additionally, under Medicare OPPS rules, not all prosthetic and DME services are reimbursed under the OPPS system—only implantable prosthetics and DME are included costs. See 42 CFR 419.2(b)(10) and (11). Indeed, the very Medicare provisions that CMS cites as providing clarity and precision contain qualifications. 42 CFR 419.2(b) lists costs that are "generally" included as outpatient hospital costs, yet explicitly does not limit the costs that may be included to those specifically listed. As CMS notes, there are Medicaid covered services that do not appear among the list of services Medicare covers and CMS rules prohibit inclusion of costs within the OPPS for "services not covered by Medicare

by statute." See 42 CFR 419.22(p). Medicare generally does not cover services for people under the age of 21-- an entire segment of the federally mandatory Medicaid population under the SSA. We respectfully maintain that some overlap must exist between services eligible for reimbursement as outpatient hospital services and other State Plan service categories and that such overlap is not inconsistent with Medicare payment principles but rather is recognized within them.

We have previously understood that the purpose of the UPL is to allow states to reasonably *estimate* the amount that would be paid for Medicaid services under Medicare *payment principles*. The proposed rule changes the fundamental comparison behind the UPL from the theoretical question of what Medicare *would have* paid for a *Medicaid* service, to what would Medicare pay for a Medicare service. We understand CMS's desire to establish standard references that all States may use to calculate the UPL, but respectfully ask CMS to develop alternative means of achieving this end without disregarding fundamental differences between the two programs and the resulting need for flexibility in determining Medicaid upper payment limits.

Access to Services: Hospitals deliver on an outpatient basis certain services that states must provide under the Medicaid statute (e.g., EPSDT), or that are particularly difficult for Medicaid recipients to access (e.g., dental), but which would no longer be considered outpatient hospital services under this NPRM. It is not clear what upper payment limits, if any, would apply to these redesignated services. If payments to hospitals for services they provide were subject to community upper payment limits, it is likely that Medicaid payment levels could not recognize hospitals' necessary overhead in providing these services in their facilities. Artificially limiting the scope of outpatient hospital services in order to reduce payments to hospitals would not only undermine Congress' intent in designating outpatient hospital services as mandatory Medicaid services, it is also likely to create access problems if hospitals determine Medicaid payments are insufficient to support their provision of those services. We request that CMS regulations allow for payment levels to hospitals that recognize the value of the services they provide to our most vulnerable citizens, and foster continued access to those services.

In addition to these overarching concerns, Massachusetts has the following additional comments, questions, and concerns regarding the proposed rule.

Provisions of the Proposed Rule

1) Please clarify the effective date for this proposed rule in light of the moratorium on related Medicaid rules.

Part 440 – Services General Provisions

Outpatient clinic and hospital facility services and rural health clinic services (Proposed 42 CFR 440.20)

1) What, if any, overlap is there between **42 CFR 440.20,** and the recently proposed rule governing Medicaid coverage for rehabilitative services under **42 CFR 440.130(d),** and diagnostic services under **42 CFR 440.130(a)?** How may states reconcile these provisions?

2) If a service is included in the Medicare OPPS, but is also specified in Medicaid regulations as a separate State Plan category of service, is that service considered an outpatient hospital services under the new rule when furnished in an outpatient hospital facility? If not, what is the justification for treating a service as a hospital service under Medicare, but not under Medicaid?

3) Bundled outpatient hospital rates were developed to provide incentives to hospitals to deliver care in an efficient manner and to discourage overutilization of services—an incentive that is inherent to fee-for-service systems. Although Medicare's OPPS is a bundled rate method, some states' outpatient hospital payment methods achieve an even greater degree of bundling than Medicare's OPPS. The current proposed rule would negatively impact states' efforts to foster efficiency and promote appropriate incentives by effectively forcing states to separate from their bundled outpatient hospital payment methods, any service that could not be included in its outpatient hospital UPL under the NPRM. Please explain the rationale behind eliminating states' ability to pay hospitals bundled rates for outpatient services in a way that exceeds the efficiencies recognized by the Medicare OPPS.

4) While 42 CFR 440.20(a)(4) purports to limit the scope of outpatient hospital services to those services that Medicare pays for as outpatient hospital services, 42 CFR 440.20(a)(5) creates an ambiguity that appears to be inconsistent with that limitation. 42 CFR 440.20(a)(5) provides that outpatient hospital services "[m]ay be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of 'outpatient hospital services' those types of items and services that are not generally furnished by most hospitals in the State." That provision has been interpreted, in the context of eliminating optional benefits, to mean that Medicaid agencies may *not* exclude from the definition of outpatient hospital services those types of items and services that *are* generally furnished by most hospitals in the State.

Please explain how states should apply **42 CFR 440.20(a)(5)** when services generally provided by hospitals in the state are outside the Medicare outpatient hospital payment method, or are also specified in Medicaid regulations as a separate State Plan category of service. Are such services mandatory outpatient hospital services? Would the determination no longer be state-specific? Please clarify the rule to eliminate any inconsistency or ambiguity between 42 CFR 440.20(a)(4) and (a)(5).

5) Please clarify the difference, if any, between 'non-traditional hospital services' and services that are provided in hospital outpatient settings but are not included in the Medicare OPPS or alternative Medicare outpatient hospital payment method?

6) What is the significance of the revision to the title of 42 CFR 440.20 to add the word 'clinic' if the regulation itself has no changes regarding 'clinic services' and where 'clinic services' are defined at 42 CFR 440.90?

Part 447 – Payments For Services

Outpatient hospital and clinic services: Application of upper payment limits (Proposed 42 CFR 447.321)

1) This NPRM narrows the definition of outpatient hospital services and specifies only the upper payment limit ("UPL") that applies to that narrower set of outpatient hospital services and clinics. This leaves unaddressed what upper payment limits, if any, apply to services that would no longer be considered outpatient hospital services and for which an upper payment limit is not specified in the Medicaid statute or regulations. This raises a particular concern where, in the absence of a Medicaid UPL regulation applicable to a particular service (e.g., physician service), CMS has recently required states to utilize a specific and evolving UPL calculation that is not articulated in any statute, regulation, or even sub-regulatory material.

Please clarify what UPL, if any, applies to each service that is provided in hospital outpatient facilities, but which would not be within the scope of the definition of outpatient hospital services under 42 CFR 440.20.

Please clarify how a state should deal with clinic types that offer Medicaid services which have no Medicare equivalent—such as family planning clinics.

2) The preamble (though not the proposed regulation itself) requires uniform trending of all data to the current rate year using the Medicare Market Basket Index; however, the preamble also states that States must demonstrate their methodology for any proposed volume trending.

Please clarify what data (i.e. charges, payments, and/or costs) must be trended using the Medicare Market Basket Index and clarify whether this applies to Medicare data only, or to Medicaid data as well.

Please clarify whether volume measures should also be trended uniformly using the Medicare Market Basket Index, or whether states have discretion in what trend to apply to volume.

The impact of this proposed trend factor varies depending upon how CMS requires it to be applied. If the trend applies only to Medicare cost, charge and payment data, this would not appear to be problematic. However, it is not clear whether and why CMS would require a Medicare trend factor be applied to Medicaid cost, charge and payment data. Furthermore, as CMS has recently indicated to our state, it wants to see the hospital-

specific UPL calculations that support the class-wide UPL. Applying a uniform trend factor to Medicaid data or to volume data would contradict that guidance.

Any requirements CMS will impose on states regarding calculation of the UPL should be included in the regulation itself.

3) Please clarify how a state should account in its UPL calculation for mandatory outpatient hospital services pursuant to 42 CFR 440.20(5) that are not covered by Medicare as outpatient hospital services, or are also specified in Medicaid regulations as a separate State Plan category of service.

4) With respect to Option 1, the preamble, but not the regulation, indicates that under the first option a state with a percentage below 100% could make supplemental payments up to 100% of what Medicare pays, but would have to demonstrate per CPT code what Medicare would pay for the equivalent Medicaid services, and submit documentation for a clinic UPL demonstration. Any requirements CMS will impose on states regarding calculation of the UPL should be included in the regulation itself.

5) With respect to Option 2, the preamble, but not the proposed regulation indicates that (1) a UPL demonstration would be required under option 2 showing a comparison by CPT code of the amount paid by Medicare for Medicaid equivalent services, and (2) an option 2 state could pay more than Medicare for some services or facilities as long as the aggregate Medicaid payment was equal to or less than the amount Medicare would pay in the aggregate. Any requirements CMS will impose on states regarding calculation of the UPL should be included in the regulation itself.

Massachusetts appreciates the opportunity to comment on this proposed rule and looks forward to continuing to work with CMS to strengthen and improve the Medicaid program.

Sincerely,

/s/

Tom Dehner
Medicaid Director

STATE OF COLORADO

DEPARTMENT OF HEALTH CARE POLICY & FINANCING

1570 Grant Street
Denver, CO 80203-1818
(303) 866-2993
(303) 866-4411 FAX
(303) 866-3883 TTY

Bill Owens
Governor

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-2213-P
Mail Stop C4-26-05
7500 Security Blvd.
Baltimore, Maryland 21244-1850

Re: Commentary on proposed rule. Reference file code CMS-2213-P

Madams and Sirs,

The Colorado Department of Healthcare Policy and Financing, which administers the Colorado Medical Assistance Program, provides the following commentary and questions regarding the proposed rule revision for Medicaid hospital outpatient services.

Thank you for your attention to these concerns. You may contact me at eric.wolf@state.co.us or by phone at 303-866-5963.

Sincerely,

Eric C. Wolf MPA RN
Hospital Program Coordinator

Attachment: commentary on proposed rule CMS-2213-P (2 pages)

Commentary on proposed rule. Reference file code CMS-2213-P

Regarding the types of services to be included or excluded from outpatient hospital services:
The article states:

> In our review of Medicaid State Plans, we have noted instances where the State allows non-facility services and/or nontraditional outpatient hospital services to be paid under the outpatient hospital benefit. The definition of outpatient hospital services in current regulation may allow States to include such nonfacility services (that is, physician and professional services) and/or nontraditional outpatient hospital services (that is, school-based and rehabilitative services) within the State Plan definition of outpatient hospital services. We do not believe that such a broad definition of outpatient hospital services is consistent with congressional intent when enacting section 1905(a)(2)(A) of the Act (p. 55160).

and the article states:

> We are proposing to exclude non-facility and/or nontraditional hospital services from the outpatient definition in this proposed rule to assure efficiency and economy within the scope of outpatient hospital services as outpatient service rates are generally higher than rates for other Medicaid non-facility services (p. 55161).

Question: The proposed rule change does not reference the terms "traditional, "non-traditional," facility services," or "non-facility services." There are no definitions for these terms either in this discussion or in the proposed rule. Therefore we are unable to determine what limitations on outpatient services CMS is proposing, if any limitations are proposed at all.

Regarding the effect of the rule change on payments for services:
The article states:

> ...there have been instances of claims for payment of physician services as outpatient hospital services, which result in payment far in excess of the rates available in the State for physician services" (p. 55159).

and the article states:

> We believe the fiscal impact would be minimal because most States historically have not made supplemental payments to private providers up to the upper payment limit (pp. 55164 – 65).

Question: How extensive is the issue of inappropriate payments? Exactly what is meant by "far in excess"? Is there another way of addressing the concern?

Regarding the appropriateness of a broad definition of hospital outpatient services

Questions: Hospitals are affiliated with other provider types (FQHC, RHC, etc.) and are likely, if required to, to shift billing to other provider numbers. It is also possible that the additional business costs of developing separate agencies for the affected services might result in denial of necessary services in small frontier or rural communities. How would CMS address this concern?

If a small community has only a hospital with its hospital-based clinics and services, and there are no competitors, would it still be inappropriate for the hospital to offer a broad range of outpatient services?

Regarding hospital oversight and control

The article states,

> ...the current broad definition does not clearly limit the scope of the outpatient hospital service benefit to those services over which the outpatient hospital has oversight and control (p. 55159).

Questions: Can CMS be more specific about how a hospital has or does not have oversight and control of services provided through its outpatient department? What activities are occurring that, according to information CMS has received, are not under the control and oversight of the hospital? What level of oversight and control are considered appropriate by CMS?

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Rural Hospital Coalition, Inc.

14116 Denham Road ◊ Pride, LA 70770 ◊ Phone (225) 389-9429 ◊ Fax (225) 387-0309 ◊ Email larhc@aol.com ◊ www.larhc.org

October 16, 2007

Via Federal Express

Centers for Medicare & Medicaid Services
Office of Health and Human Services
Attention: CMS-2213-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-2213-P--Outpatient clinic and hospital services facility services definition

We are writing on behalf of the membership of Louisiana's Rural Hospital Coalition, Inc. regarding the outpatient clinic and hospital services facility services definition proposed rule published at 72 Fed. Reg. 55158 (Sept. 28, 2007). The forty-one (41) members of the Coalition are rural hospitals, which provide much needed care in Louisiana's medically underserved areas, including the Mississippi and Red River delta regions which are among our nation's most impoverished.

Several years ago, CMS tried unsuccessfully to exclude the costs of such hospital-based rural health clinic (RHC) services from disproportionate share hospital (DSH) funding. That past attempt by CMS was struck down by the courts. Louisiana Dept. of Health and Hospitals v. CMS, 346 F.3d 517 (5th Cir. 2003). Because the Court found CMS' rejection of Louisiana's state plan inconsistent with the Social Security Act, we do not believe that CMS may reverse the decision by rule. Congress, not CMS, must change the eligibility of hospital-based RHC's for inclusion in DSH calculations.

As the Fifth Circuit recognized, "the broad goal of the DSH program [is] to support hospitals that serve low-income patients." Congress has, on multiple occasions, demonstrated an intention of broadly defining the DSH program. See, e.g., H.R. Rep. No. 100-391, at 524-27 (1987) (demonstrating: (1) Congress's solicitude for the needs of rural hospitals by exempting them from certain requirements otherwise applicable to DSH hospitals, and (2) Congress's awareness of state plans that offer extra payments to some hospitals because they provide "outpatient services and outpatient pharmacy to Medicaid and non-Medicaid eligible low-income patients"); H.R. REP. NO. 101-964, at 868, 871 (1990) (explaining new provision in § 1396r-4(c)(3) that allows additional DSH payments to designated hospitals to finance services for Medicaid and low-income patients).

The hospital-based RHCs that CMS is again attempting to exclude from DSH eligibility function as part of the hospital, and help rural hospitals provide the same care previously provided by the emergency department, but in a more clinically appropriate and less costly setting. 346 F. 3d at 577. Ironically, under CMS' proposed rule, more expensive uncompensated emergency room care would be encouraged and covered, but uncompensated hospital-based RHC care would be discouraged and not be included in DSH-eligible costs.

The Fifth Circuit explained that including the costs of such RHC services in the costs of the hospital for disproportionate share furthered the Congressional purpose in enacting the DSH legislation:

> **Louisiana contends that the Administrator's interpretation—which precludes reimbursement to hospitals for uncompensated care provided in their RHCs even though the same care provided to the same patients in a less clinically appropriate and more costly emergency room would be covered—is antithetical to the intention of Congress. Here too it seems that Louisiana presents the stronger argument.**

346 F.3d at 578.

CMS partially justifies its rule making by stating only one state plan defines RHC services as outpatient services. We submit this comment is self serving and tainted, in that CMS has controlled what has been approved in the state plans and would have done the same in Louisiana, absent the Fifth Circuit decision regarding Louisiana.

CMS' proposed rule undermines well-established public policy. Rather than reward use of cheaper and more appropriate RHC services, it does just the opposite. The proposed rule actually creates financial incentives to use scarce and expensive emergency department services, even though hospital-based RHC services can be provided at a fraction of the cost and do not tie up critical emergency care resources. CMS' proposed rule creates exactly the wrong incentive.

Our rural hospitals have attempted to end the burden placed on emergency rooms that are used for primary care. Now, CMS is attempting to reestablish the use of the emergency department for routine medical care by those who are unable to afford other forms of care. This is not appropriate. Use of hospital-based RHC's should be encouraged, not discouraged, because RHC use will save taxpayer dollars.

The proposed change will have an especially severe impact on our constituents, because the state is still recovering from Hurricanes Katrina and Rita and burdened by the poverty and lack of education in the Delta region. Uncompensated care costs to rural hospital-based RHC's – many of which hospitals are already running at a deficit– will exceed four million dollars. This additional shortfall will further limit the rural hospitals' ability to provide the increased volume of uncompensated care that they have been asked to provide after the 2005 storms and the continued problems of the Delta region.

We ask that you please withdraw the proposed rule, docketed under CMS-2213-P- relating to the outpatient clinic and hospital services facility services definition.

Sincerely,

Linda K. Welch

Linda K. Welch
Executive Director

/lfv

23

HURLEY

Patrick R. Wardell
President & Chief Executive Officer

October 29, 2007

Mr. Kerry N. Weems, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, D.C. 20201

Ref: CMS-2213-P — Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit

Dear Mr. Weems:

I am writing on behalf of Hurley Medical Center to express our serious concern regarding the issuance of the above-referenced Proposed Rule.[1] This Rule (1) unnecessarily narrows the definition of outpatient hospital services, with a significant but unacknowledged impact on disproportionate share hospital (DSH) payments; and (2) is overly prescriptive in dictating upper payment limit (UPL) methodologies for private outpatient hospitals and clinics. Of more concern, however, the Proposed Rule violates a recent legislative moratorium[2] (the Moratorium) on implementation of a cost limit on payments to governmental providers or restrictions on Medicaid graduate medical education (GME) payments. For these reasons, Hurley Medical Center urges CMS to withdraw the Proposed Rule immediately.[3]

WHO WE ARE – An Overview of Hurley Medical Center:

It is important to put into context, the impact that implementation of this Proposed Rule would have on Hurley Medical Center by explaining Hurley's role in the local Genesee County community, as well as the significant role we play throughout the entire state of Michigan as the region's safety net provider. While 57.5% of our patients come from Flint, 29.1% of the patients we serve live outside the City of Flint, but within Genesee County, and 13.4% of our patients come from various other regions throughout the state.

[1] 72 Fed. Reg. 55158 (Sep. 28, 2007).
[2] U.S. Troop Readiness, Veterans' Care, Katrina Recovery and Iraq Accountability Appropriations Act of 2007, Pub. L. No. 110-28, Section 7002(a).
[3] Hurley does not concede through submission of these comments that CMS has the authority to propose these provisions, nor to request, receive or review related comments, during the period of the moratorium.

Hurley is the largest hospital in Genesee County with 461 beds and is this region's premier public medical center and teaching hospital, providing safe, reliable, high-quality care for thousands of Genesee County residents each year. Additionally, Hurley is one of the largest employers in Genesee County and provides more than 2,200 jobs to local residents. Nine (9) unions represent Hurley's employees. As you can see, based on these facts, the financial status of Hurley has a direct impact on the economic status of our entire community. It is therefore important that you understand the total economic impact this proposed Rule will have on the Flint and Genesee County community, as well as on our patients throughout the state. This loss will negatively impact the vital services we are able to offer all our patients, particularly in the area of specialized services.

Hurley Medical Center is the only medical center in the region that provides specialty care in: Trauma, emergency and critical care services, advanced burn center, kidney transplantation, neonatal intensive care, pediatric intensive care, high risk pregnancy care, and psychiatric services. The volume of patients seeking care and treatment at Hurley is tremendous. In 2006, Hurley served 24,495 inpatients. The number of outpatient visits totaled 472,208. The number of babies born at Hurley was 2,824 and more than 78,084 patients visited Hurley's Emergency Department. We treat, on the average, at least 1450 patients a week in our Emergency Room Department. Almost 20 percent of Genesee County residents rely on Medicaid. One in five children in Genesee County lives in poverty. 27 percent of the people of Flint live in poverty, significantly more than the national average of 11.7 percent. The Flint and Genesee County community, particularly the poor, has depended on Hurley Medical Center for the past 100 years. This dependence is slowly spreading throughout the state, as our patient base grows each year.

As the region's safety net provider, it is Hurley's mission to provide care to everyone, without regard to ability pay. As the primary Medicaid health care provider in the region, Hurley provides more than $20 million a year in uncompensated care to the community. We are still analyzing the potential negative dollar amount impact this Proposed Rule would have on Hurley, however, we can say at this point that any reduced revenue as a result of this Proposed Rule will adversely impact Hurley's ability to continue to provide medical services critical to the communities we serve and will put those services in serious jeopardy. We also serve a critical role in our community of ensuring access to ambulatory care for uninsured and Medicaid patients. The vast majority of the 472,208 outpatient ambulatory care visits is reimbursed as outpatient hospital services.

Additionally, we rely on rely upon Medicaid disproportionate share hospital (DSH) and other supplemental payments, including supplemental outpatient payments, for survival.

Our key points of objection are the following:

- CMS has violated the congressional Moratorium and, in any event, failed to clarify how this Proposed Rule interacts with the Moratorium.

- The Proposed Rule will have a potentially significant impact on DSH payments, which CMS does not acknowledge.
- The Proposed Rule discourages hospitals from expanding important ambulatory care services.
- The Proposed Rule ignores significant differences in the scope and purposes of the Medicaid and Medicare programs in requiring coterminous coverage of outpatient hospital services, and in any event requires clarification.
- CMS' definition of outpatient hospital services to exclude services otherwise covered by the State Plan is not required by the Medicaid statute and is inconsistent with language in the preamble to the Proposed Rule.
- The overly prescriptive proposed outpatient UPL excludes the costs of interns and residents, potentially resulting in millions of dollars in losses for providers in certain states, reduces state flexibility, and does not capture all Medicare-covered costs.
- The proposed private clinic UPL prohibits cost-based reimbursement without justification and includes a circular definition of the UPL for otherwise excluded dental services.

We concur in the comments detailed by the National Association of Public Hospital (NAPH) in terms of the policy and technical concerns with the above referenced aspects of the Proposed Rule.

Because the Proposed Rule violates the Moratorium, we believe that CMS is legally obligated to withdraw it, and we vehemently urge you to do so immediately. Congress enacted the Moratorium specifically to prevent CMS from taking "any action" to develop new policies in areas in which this Proposed Rule purports to regulate. Moreover, the Proposed Rule is bad policy, and would have a significant negative financial impact on both governmental and private hospitals serving Medicaid and uninsured patients. Coming in the wake of several other regulations issued by CMS that would impose large cuts on these hospitals—including the rule imposing a governmental provider cost limit and restricting sources of non-federal share funding,[4] the rule to eliminate Medicaid funding for graduate medical education,[5] and the proposed rule which has never been finalized adopting narrow new DSH policies[6]—CMS' latest administrative action would be devastating to public, teaching and other safety net hospitals. Cumulatively these rules would eviscerate the health care safety net as well as jeopardize care for all Americans in communities across the country.

[4] 72 Fed. Reg. 29748 (May 29, 2007).
[5] 72 Fed. Reg. 28930 (May 23, 2007).
[6] 70 Fed. Reg. 50262 (Aug. 26, 2005).

We join the NAPH in urging you to consider the cumulative effect of the ever more restrictive Medicaid policies on the nation's safety net and the patients who rely on it for care. In addition to covering care for eligible populations, Medicaid supports an institutional safety net of health care providers that are critical to the well-being of their communities. If enacted, these rules would mean that such providers will no longer be able to train the next generation of doctors and health care professionals, to serve as the health care backbone of local emergency response systems, to provide critical yet under-reimbursed specialized services such as trauma care, burn care, neonatal intensive care and emergency psychiatric care, or to provide access where none would otherwise exist for the nation's poor, uninsured and underinsured individuals. Absent a more thorough analysis of real world implications of proposed policies and their impact on the health care system, we are relying on Congress to stop these policies in their tracks. Accordingly, we urge you to withdraw this regulation and all of the above mentioned pending regulations immediately. We urge you to adopt policies that strengthen, rather than dismantle, essential components of our nation's health care infrastructure and offer to work with you in developing such policies.

Thank you for your anticipated reconsideration of this vital issue.

Respectfully,

Patrick R. Wardell
President & Chief Executive Officer

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TMC
TRUMAN MEDICAL CENTERS
Better. For Everyone.

Office of the President

October 29, 2007

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, D.C. 20201

RE: CMS-2213-P- Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit

Dear Mr. Weems:

I am writing on behalf of Truman Medical Centers (TMC) in opposition to the proposed rule referenced above. This rule jeopardizes an estimated $10 million or more annually in Medicare/Medicaid funding for our hospital. The Proposed Rule violates a recent legislative moratorium on implementation of a cost limit on payments to governmental providers or restrictions on Medicaid graduate medical education (GME) payments.

TMC is Western Missouri's tier 1 Trauma Center and is staffed to accept critically ill and injured patients 24 hours a day. Currently three in four patients are Medicaid-eligible or uninsured. Last year TMC provided about $80 million in uncompensated services at cost and over $145 million in Medicaid services. Furthermore, TMC treats Kansas City, Missouri's most vulnerable population including the elderly and low-income families as well as individuals with chronic health challenges such as Diabetes, Asthma, HIV/AIDS, Sickle Cell and severe mental illnesses. Additionally, TMC delivers almost half of the babies born yearly in Kansas City, Missouri and operates one of the area's busiest Neonatal Intensive Care Units.

If promulgated, these proposed rules would threaten TMC's ability to continue providing necessary outpatient medical services to the community. Because of the increasing uncompensated care burden, TMC is under extreme financial stress. Over the last two years, TMC has accumulated a loss of $20 million dollars and is currently unable to make needed capital purchases. Futher reductions in funding would seriously curtail TMC's ability to provide many of the community-based primary and preventive Ambulatory Care services to our most at-risk population.

Because we feel the proposed rule violates the Moratorium, we urge CMS to withdraw it.

TMC also has major concerns regarding the proposed rule's financial impact as well as the impact on community health services:

- **Impact on Medicaid DSH**
  While this is not acknowledged by CMS, the proposed rule will significantly reduce our Medicaid Disproportionate Share Reimbursement by eliminating many of the uncompensated outpatient services from a hospital's DSH cap.

- **Outpatient Interns and Resident Costs**
  The proposed rule would reduce outpatient reimbursement for interns and resident costs which are a direct violation of the Moratorium, and would also result in a loss of dollars needed to educate and train the community's future doctors and other health care professionals.

- **Definition of Outpatient Services**
  CMS's decision to eliminate reimbursement for Medicaid services covered in the State Plan is not consistent with the Medicaid statute. It ignores significant differences in the scope and purpose of the Medicare and Medicaid programs.

- **Encourages Reductions in Key Ambulatory Care Services**
  Besides eliminating DSH reimbursement, the new rule eliminates hospital overhead from many hospital ambulatory services. This discourages safety net facilities from providing many of the community-based primary and preventive ambulatory care services that are extremely effective tools in improving community health and reducing future health care costs.

Based on the devastating impact this proposed rule would have on TMC and the health of the Kansas City, Missouri community we urge CMS to withdraw this regulation.

If you have any questions about this matter, please contact Gerard Grimaldi at (816) 404-3505.

Sincerely,

John W. Bluford
President/CEO

JWB/gg/sh

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North Carolina Department of Health and Human Services
Division of Medical Assistance
2501 Mail Service Center • Raleigh, N. C. 27699-2501
Tel 919-855-4100 • Fax 919-733-6608

Michael F. Easley, Governor
Dempsey Benton, Secretary

William W. Lawrence, Jr., M.D., Acting Director

October 29, 2007

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

RE: CMS – 2213-P - Medicaid Program; Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit (Vol. 72, No. 188), September 28, 2007

Dear. Mr. Weems:

The North Carolina Division of Medical Assistance welcomes the opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS) proposed rule regarding changes to Medicaid policy as it relates to federal clarification of outpatient clinic and hospital facility services definition and the upper payment limit of those services. North Carolina strongly opposes this CMS proposed rulemaking change to Medicaid policy.

As stated in the September 28, 2007, Federal Register, page 55161, CMS recognizes that Medicaid covers more services than Medicare; however, it is CMS' opinion that an "economic and efficient UPL should include only services to which there exists a Medicare equivalent". By taking this position, CMS is denying reimbursement of Medicaid costs for a significant segment of North Carolina's Medicaid population, children, pregnant women, and young adults. At a minimum, the UPL for outpatient services should be the Medicaid cost as allowed by the CMS Provider Reimbursement Manual 15 and calculated using the CMS 2552 cost reporting methodology.

The Division of Medical Assistance appreciates the opportunity to comment and express its concerns regarding the proposed rules. If CMS has any questions or needs clarification, DMA personnel will be pleased to respond.

Sincerely,

William W. Lawrence, Jr., MD

Cc: Dempsey Benton
Dan Stewart
T. H. Galligan
Roger Barnes
North Carolina Hospital Association
National Association of State Medicaid Directors