JUDGE DAVID L. BAZELON CENTER FOR MENTAL HEALTH LAW
Civil Rights and Human Dignity

October 18, 2007

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

FILE CODE: CMS-2213-P

Dear Sir or Madam:

The following comments are submitted by the Bazelon Center for Mental Health Law, a legal advocacy organization dedicated to upholding the rights of persons with mental illness, concerning the proposed rule, published on September 28, 2007, regarding clarification of the outpatient clinic and hospital facility services definition and upper payment limit.

We found this rule to be confusing, both in its preamble and in the language of the regulation itself. Outpatient hospital services for persons with mental illness should, and do, include the important psychiatric rehabilitation and targeted case management services authorized by Medicaid under Section 1905 of the Social Security Act.

This rule redefines outpatient hospital services and limits them to the services covered by Medicare and then defines the rates that will be allowable for these services. The preamble states that this proposed regulation "would clarify the scope of services that may be included in the State Plan definition of outpatient hospital services."

In fact, as we understand it, that is not strictly the case. This rule outlines the payment methodology for basic, Medicare-covered, outpatient hospital services. It is not an exhaustive definition of all services that may be provided through a hospital outpatient department or clinic. These facilities/clinics are still permitted to bill Medicaid for any additional Medicaid-covered services that they furnish, such as rehabilitation or targeted case management.

Assuming the above interpretation is correct, we strongly urge that the proposed rule be amended to make it explicitly clear that other covered-Medicaid services may be furnished to outpatients and that hospital outpatient departments and clinics are eligible for reimbursement for such services.

If our interpretation is not correct, and CMS in fact intends to deny these other services in these settings, we would challenge the agency's authority to make such a sweeping change in covered Medicaid services.

Thank you for considering our comments.

Sincerely,

Chris Koyanagi

Chris Koyanagi
Policy Director

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

Dear Secretary Leavitt:

We are writing to object to the outpatient clinic and hospital services facility services definition proposed rule that was published in the Federal Register on September 28, 2007. Your reference is CMS-2213-P-- Outpatient clinic and hospital services facility services definition.

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 rural health clinics personnel, pays all the expenses of the rural health clinic, performs quality assurance responsibilities, and credentials the physicians and physician assistants employed by the rural health clinic. 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 will limit our hospital's ability to provide services at the RHC, because disproportionate share funding covers much of the cost of the RHC's services. This will limit our ability to provide care to those who need it most and are unable to pay for it.
Our area, like the rest of the state, faces a severe problem with increased emergency room use by patients who actually only need clinic services. Because they can be seen in the emergency department (eventually), and due to EMTALA regulations, patients know they can not be turned down. Patients with no insurance traditionally and regularly have used the emergency department like a primary care clinic.

Such improper use of the emergency department by indigent patients straines our hospital's limited resources. It also makes it difficult for those patients to get timely care.
Our hospital-based RHC solved this problem by giving those patients a less expensive and readily-available alternative to the emergency room. This allowed us to meet their needs in a timely manner and at a much lower cost.

In short, CMS' effort to exclude our hospital-based RHC's costs in disproportionate share calculations is a terrible idea because it removes much needed monetary support for the RHC's hospital-based clinic services, and increases the costs of the Emergency Rooms. 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 proposed definitions will have a cruel and dire financial impact on our hospital. The loss of any revenue to a rural hospital is dire and this after all the other cuts over the last 4 years would simply close our facility.

Sincerely,

HeatherAnn M. O'Clair-Clark, CEO,
Caldwell Memorial Hospital
Columbia,La.

Parish of Cameron

LOWER CAMERON HOSPITAL SERVICE DISTRICT

5360 West Creole Hwy.
Creole, LA 70632
Phone: 337-439-8111

October 24, 2007

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2213-P
Mail Stope 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:

We are writing to object to the outpatient clinic and hospital services facility services definition proposed rule that was published in the Federal Register on September 28, 2007. Your reference is CMS-2213-P - Outpatient Clinic and Hospital Services Facility Services Definition.

We are a small rural hospital located in Creole, Louisiana, with a hospital-based rural health clinic (RHC) that functions as part of the hospital. The hospital employs the RHC's personnel, pays its bills, performs quality assurance, credentials the physicians and physician assistants employed by the RHC, owns/leases 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 will limit our hospital's ability to provide services at the RHC, because disproportionate share funding covers much of the cost of the RHC's services. This will limit our ability to provide care to those who need it most and are unable to pay for it. 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.

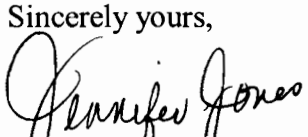
Such improper use of the emergency department by indigent patients strained our hospital's limited resources. It also makes it difficult for those patients to get timely care. Our hospital-based RHC solved this problem by giving those patients a less expensive and readily-available alternative to the emergency room. This 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.

In short, CMS's 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 proposed definition will have a severe financial impact on our hospital, which will further limit our ability to provide the increased amount of uncompensated care that we have been asked to provide after the 2005 storms that devastated our state.

Kindest regards.

Sincerely yours,



JENNIFER JONES

JJ/pk
cc: Ms. Linda K. Welch
Executive Director
Rural Hospital Coalition, Inc.

North Caddo Medical Center

The Heart of Community Healthcare Since 1965

October 23, 2007

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

Dear Secretary Leavitt:

We are writing to object to the outpatient clinic and hospital services facility services definition proposed rule that was published in the Federal Register on September 28, 2007. Your reference is CMS-2213-P-- Outpatient clinic and hospital services facility services definition. We are a small rural hospital located in Vivian, Louisiana, with a hospital-based rural health clinic (RHC) that functions as part of the hospital. The hospital employs the RHC's personnel, pays its bills, performs quality assurance, credentials the physicians and physician assistants employed by the RHC, leases 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 will limit our hospital's ability to provide services at the RHC, because disproportionate share funding covers much of the cost of the RHC's services. This will limit our ability to provide care to those who need it most and are unable to pay for it. 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 strained our hospital's limited resources. It also makes it difficult for those patients to get timely care. Our hospital-based RHC solved this problem by giving those patients a less expensive and readily-available alternative to the emergency room. This 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. 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 proposed definition will have a severe financial impact on our hospital, which will further limit our ability to provide the increased amount of uncompensated care that we have been asked to provide after the 2005 storms that devastated our state.

Sincerely,

David Jones
C.E.O.

1000 South Spruce Street • P.O. Box 792 • Vivian, LA 71082 • 318-375-3235 • Fax 318-375-5989

Abbeville General Hospital

118 North Hospital Drive
P.O. Box 580
Abbeville, Louisiana 70511-0580

October 22, 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:

We are writing to object to the outpatient clinic and hospital services facility services definition proposed rule that was published in the Federal Register on September 28, 2007. Your reference is CMS-2213-P-- Outpatient clinic and hospital services facility services definition.

We are a small rural hospital located in Abbeville, Louisiana, with a hospital-based rural health clinic (RHC) that functions as part of the hospital. The hospital employs the RHC's personnel, pays its bills, performs quality assurance, credentials the physicians and physician assistants employed by the RHC, 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 will limit our hospital's ability to provide services at the RHC, because disproportionate share funding covers much of the cost of the RHC's services. This will limit our ability to provide care to those who need it most and are unable to pay for it. 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 strained our hospital's limited resources. It also makes it difficult for those patients to get timely care. Our hospital-based RHC solved this problem by giving those patients a less expensive and readily-available alternative to the emergency room. This 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.

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 proposed definition will have a severe financial impact on our hospital, which will further limit our ability to provide the increased amount of uncompensated care that we have been asked to provide after the 2005 storms that devastated our state.

Sincerely,

Ray Landry

Ray Landry
Chief Executive Officer
Abbeville General Hospital

RL/stl

CALIFORNIA ASSOCIATION OF PUBLIC HOSPITALS AND HEALTH SYSTEMS

October 25, 2007

VIA FEDERAL EXPRESS

Mr. Kerry N. Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2213-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

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

Dear Mr. Weems:

On behalf of the California Association of Public Hospitals and Health Systems ("CAPH"), I am writing to express our concerns with, and opposition to, the proposed Medicaid rule regarding the definition of outpatient clinic and hospital facility services and the upper payment limit for these services. We appreciate the opportunity to advise the Centers for Medicare & Medicaid Services ("CMS") of the substantial effects that its proposed rule would have on California's public health care safety net. CAPH urges you to withdraw this rule.

This proposed rule, if finalized, would likely result in the reduction of critical health care services that public hospitals are uniquely qualified to provide, thereby limiting services and health care access—a result directly contrary to the purpose of the Medicaid program. CAPH represents 20 public hospitals, health care systems and academic medical centers, located in 16 counties in California. Our hospitals are a cornerstone of the State's health care system. Public hospitals operate nearly 60% of California's top-level trauma centers, which are state-of-the-art emergency medical units that treat the most catastrophic, life-threatening injuries. Our members participate in the Medicaid program by providing a comprehensive range of services to a substantial portion of the State's Medicaid population. While our members account for only 6 percent of the acute care hospitals in California, they consistently provide over 35 percent of hospital care to the State's Medicaid beneficiaries, 50 percent of the hospital care to California's uninsured, and over 80 percent of the State's hospital care to the medically indigent.

As an initial matter, the rule directly contravenes the May 25, 2007 congressional moratorium that prohibits CMS from taking any action to promulgate or implement provisions that impose cost limits on providers operated by units of government or that restrict payments for graduate medical education ("GME") under the Medicaid program.

In addition, the rule purports to make a "clarifying" change to the definition of hospital outpatient services. However, CMS makes it clear in the preamble that its intent is to apply this definition to restrict the services that may be reimbursed as hospital outpatient services under a state Medicaid program. This restriction is a substantive policy change that would go far beyond a mere "clarification." Namely, the new definition would apply to both governmentally operated and privately operated facilities, and would inappropriately limit the flexibility granted to the states under the Medicaid statute to specify the services and payment methodologies for their Medicaid programs.

The rule also would establish two methodologies for calculating the upper payment limit ("UPL") for hospital outpatient services for privately operated facilities, based on a reasonable estimate of the amount that would be paid for the services under Medicare payment principles. CAPH objects to this proposed change as it has an interest in the continued viability of private safety net providers, and is concerned that CMS may later attempt to apply this flawed methodology to governmentally operated facilities.

I. The Rule Violates The Congressional Moratorium.

The proposed rule is one of several in a series of significant policy changes CMS has charted to redefine the Medicaid program. Specifically, CMS has acted to restrict payments to safety net providers under the guise of assuring that payments are consistent with "efficiency" and "economy." In each case, CMS has defiantly refused to acknowledge the most important requirement that payments assure "quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area . . . ."[1]

Congress consistently has had to rebuff these attempts, most recently in May of this year, with the congressional moratorium on actions aimed at reducing Medicaid payments.[2] Under the moratorium, CMS is prohibited from taking any action (through promulgation of regulation, issuance of regulatory guidance, or other administrative action) for a period of one year to (a) promulgate or implement any rule or provisions similar to those contained in the proposed rule on cost limits for providers operated by units of government that was published on January 18, 2007[3]; or (b) to promulgate or implement any rule or provisions restricting payments for GME under the Medicaid program. The rule contravenes all aspects of the moratorium.

In the preamble to the proposed rule, CMS states that the proposed provisions are "completely different policy matters" than those set forth in the cost limit rule. CMS, however, is keenly aware of Congress' intent in imposing the moratorium, which was to protect payment levels for safety net providers. The proposed rule at issue here attempts to limit the scope of

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[1] Soc. Sec. Act § 1902(a)(30)(A); 42 U.S.C. § 1396a(a)(30)(A).

[2] Section 7002(a)(1)(B) of the U.S. Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007 (Pub. Law No. 110-28), signed by the President on May 25, 2007.

[3] 72 Fed. Reg. 2236 (Jan. 18, 2007).

services that can be included in the category of hospital outpatient services under the Medicaid program, thereby essentially prohibiting states from paying hospitals appropriately higher rates for the services they render, and reducing the flexibility to do so under the UPL. Thus, the proposed rule represents a different means of accomplishing the same thing CMS attempted to accomplish in the cost limit rule, namely the reduction of Medicaid payments for governmentally operated providers. CMS' promulgation of the rule is contrary to the intent of Congress and is in effect a violation of the moratorium.

The rule also directly violates the moratorium on the promulgation of any rule that would restrict payments for GME under the Medicaid program. The proposed rule would exclude reimbursement for GME based on the changes to the method by which the UPL would be calculated. In particular, under the rule the UPL for privately operated facilities would be based on either the Medicare cost-to-charge ratio in Worksheet C, Column 9 of the Medicare cost report, or on the Medicare payments-to-charges ratio from Worksheet E, Part B and Worksheet D, Part V of the Medicare cost report. This methodology excludes the costs and payments for interns and residents, and would result in the denial of payment for GME costs in direct contravention of the moratorium. CMS, however, ignores the fact that the rule would eliminate this component of payment under the Medicaid program.

Furthermore, the proposed rule would result in the exact same revisions to 42 C.F.R. § 447.321(a) contained in the January 18, 2007 proposed cost limit rule and the May 29, 2007 final rule[4] that delineate the three categories of hospitals and clinics for application of the UPL. In particular, both the cost limit rule and this proposed rule revise the category for non-state government facilities from "non-State government-owned or operated facilities" to "non-State government operated facilities." This change would therefore implement CMS' definition of providers operated by units of local government that are subject to the cost limits, which is barred by the moratorium.

As the proposed rule contravenes the moratorium in every way, CMS should withdraw it.

II. Specific Comments On Proposed Rule.

A. The Rule Constitutes A Substantive Policy Change That Is Not Supported By The Medicaid Statute Or Congressional Intent.

In the preamble to the proposed rule, CMS states that the existing regulatory definition of hospital outpatient services is broad. In particular, under the current definition set forth in 42 C.F.R. § 440.20(a), hospital outpatient services are defined as "preventive, diagnostic, therapeutic, rehabilitative, or palliative services" that are furnished to outpatients by or under the direction of a physician or dentist by a hospital that meets the requirements for participation in Medicare. By its terms, the definition expressly enables a state to include in the scope of outpatient hospital services physician services, rehabilitation services, home health agency services, and physical therapy services, among other services, that are provided by facilities defined and recognized as hospital facilities under state law.

CMS expresses concern that the definition creates "overlap" between outpatient hospital services and other covered benefits. However the precise concern is never articulated in

[4] 72 Fed. Reg. 29748 (May 29, 2007).

the preamble. This definition originally was promulgated for purposes of describing those Medicaid benefits and services that states could provide and for which they can receive federal financial participation. In this context, overlap with other service categories was expected. Specifically, when the definition was revised to allow states the flexibility to *exclude* services as outpatient hospital services in 1983, CMS noted that "States would still be required to cover the other mandatory services (such as physicians services) and some optional services when they are provided in the outpatient hospital setting . . . ."[5]

CMS seems to suggest that there is a potential for a provider to receive duplicate payments for the same service provided, but gives no example of how this could even occur. In any case, a duplicate payment can always be recovered under existing laws, so a rule change in that regard is unnecessary. Instead, it becomes readily apparent that CMS' real concern is not with "overlap;" rather it simply does not approve of state payment methodologies that provide greater reimbursement when services, such as physician services, are rendered by hospitals. CMS appears poised to use the revised definition to preclude states from establishing rates that appropriately differentiate services provided by hospitals from services provided by other provider types, such as physician offices. There is nothing in the regulatory history, however, to suggest the definition of hospital outpatient services was intended to restrict or otherwise govern state payment methodologies. CMS' intentions to apply the revised definition in this matter, as expressed in the preamble, is a new and substantive policy.

CMS attempts to justify the change to the definition of hospital outpatient services by stating that it would make the definition of such services consistent with the intent of Congress in enacting Section 1905(a)(2) of the Act.[6] This statutory provision was enacted in 1965, and has not been significantly amended. CMS references no legislative history or other support for any congressional intent behind the enactment of Section 1905(a)(2)(A) that is consistent with the proposed rule. Furthermore, CMS has amended the regulation regarding Medicaid hospital outpatient services several times since Section 1905(a)(2) was enacted over 40 years ago, but has never previously suggested that different payment methodologies for services rendered in different settings were inappropriate or that the definition of hospital outpatient services must be the same under Medicare and Medicaid.

CMS' attempt to substantively change existing policy is very apparent when viewed in light of Louisiana Department of Health and Hospitals v. CMS.[7] In that case, CMS initially advised Louisiana that if it were to create a process to license or formally approve hospital-based rural health clinics as hospital outpatient departments, then the uncompensated care costs for hospital outpatient services could be included in the disproportionate share hospital ("DSH") calculation. After the state acted in accordance with CMS' guidance, the agency, in a complete reversal of its previous position, concluded that the services provided by rural health clinics that were licensed or approved as hospital outpatient departments under state law did not fall within the meaning of hospital outpatient services, and disapproved the State Plan. The court ruled that CMS' action, in light of the existing regulatory definition and the agency's earlier position, was arbitrary and capricious. The facts in the Louisiana case clearly demonstrate that CMS has not followed a consistent interpretation of hospital outpatient services for Medicaid, and that the position reflected in the preamble is fairly recent. While administrative agencies

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[5] 48 Fed. Reg. 10378, 10380 (Mar. 11, 1983).
[6] 42 U.S.C. § 1396d(a)(2)(A).
[7] 346 F.3d 571 (5th Cir. 2003).

may in appropriate cases change their interpretation of a statutory or regulatory term, the agency must acknowledge that this is in fact what it is doing, rather than simply referring to such changes as "clarifications" that "would not significantly alter current practices."

The key components of the revised definition, that the definition of Medicaid hospital outpatient services conform with the Medicare scope of covered outpatient services, and that the Medicare provider-based requirements be applied, also are significant departures from prior CMS policy that create uncertainty for existing payment methodologies. The application of standards developed exclusively for Medicare program purposes is not appropriate for Medicaid payment purposes. First, there are numerous services that are specifically excluded from Medicare coverage that may be covered by a state under its Medicaid program. These services include dental services, vision care, foot care and immunizations.[8] As these services are not covered by Medicare, they are not paid by Medicare under the Outpatient Prospective Payment System ("OPPS") or under an alternative payment methodology, and therefore would have to be excluded from hospital outpatient services for Medicaid purposes. That these services are not covered by Medicare does not provide a basis for prohibiting them from being reimbursed as hospital outpatient services under Medicaid.

The treatment of dental services is one example of CMS' failure to thoroughly think through the inherent differences between the two programs. Under the Medicare statute and regulations, dental services are specifically excluded from coverage unless the procedure requires inpatient hospitalization.[9] Accordingly, there is no Medicare coverage or payment for hospital outpatient services for dental care, whether under the OPPS or under an alternate payment methodology. In contrast, the Medicaid statute and regulations provide that dental services are one of the optional services that a state may choose to cover under its Medicaid program.[10] In the rule, CMS proposes no change to the Medicaid definition of hospital outpatient services as including services furnished to outpatients by or under the direction of a dentist.[11] However, the proposed rule would eliminate all dental services from the Medicaid definition of hospital outpatient services because they are not within the scope of services that would be paid as outpatient services by Medicare. If that is CMS' intent, then it is unclear why it did not remove the reference to services "furnished by or under the direction of a . . . dentist" from the definition of hospital outpatient services, as that part of the regulation would be mere surplusage and of no meaning if the rule is adopted.

Second, the Medicare provider-based requirements were established specifically for the Medicare payment methodology for outpatient services. In past guidance on the Medicare provider-based rules, CMS has given states flexibility to determine whether to apply the Medicare provider-based rules to Medicaid outpatient services. In 2001, CMS indicated that states "have considerable flexibility to determine appropriate payment rates in their State Medicaid plans and could adopt higher payment rates" for services at freestanding facilities.[12] Later, CMS expressly rejected a suggestion that it prohibit states from applying the provider-based criteria in determining payment under Medicaid. Rather, CMS stated that "a State may

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[8] 42 U.S.C. § 1395y(a); 42 C.F.R. § 411.15.

[9] 42 U.S.C. § 1395y(a)(12); 42 C.F.R. § 411.15(i).

[10] 42 U.S.C. §§ 1396a(a)(10) and 1396d(a)(10); 42 C.F.R. § 440.100.

[11] 42 C.F.R. § 440.20(a)(2).

[12] Provider Based Issues Frequently Asked Questions, FAQ #10 (July 2001).

adopt payment methods that do not differentiate between facilities that meet the provider-based requirement and those that do not. To the extent that States amend their State plans to contain such payment methods, we do not object to these actions. However, we do not believe it would be consistent with State flexibility to prohibit States *that wish to apply* provider-based criteria in making their payment decisions from doing so."[13]

CMS historically has recognized that states have flexibility in determining whether to apply the Medicare provider-based requirements for Medicaid hospital outpatient services. We believe this is appropriate given that the Medicare provider-based rules were developed for Medicare services and not for Medicaid services. Indeed, some states have established provider-based requirements, while others have not. In some cases, states have adopted provider-based requirements which are actually more stringent than the Medicare requirements. The proposal to apply the Medicare provider-based requirements to all Medicaid outpatient services make little sense given the different methodologies used by states to pay for hospital outpatient services. It is not clear how CMS concluded that only one state would be affected by the proposed rule. For these reasons, we believe CMS should not alter the Medicaid definition by applying the Medicare scope of covered hospital outpatient services and the Medicare provider-based requirements.

B. The Proposed Restrictions On Medicaid Hospital Outpatient Services Would Inappropriately Limit The Flexibility Granted To The States.

In the preamble, CMS acknowledges the states' broad flexibility to establish payment methodologies and rates. Notwithstanding this acknowledgment, one of CMS' key rationales for the proposed rule is to prohibit states from providing increased payment rates for services rendered by hospitals, more specifically, "payment for identical services of a higher amount under the outpatient hospital benefit." CMS gives no basis for its claim that the services it seeks to exclude from hospital outpatient services are "identical" to services rendered in other settings, nor does it give any reason as to why the higher payment amounts are inappropriate.

The approach taken by CMS in the proposed rule is fundamentally flawed. In particular, the regulation at 42 C.F.R. § 440.20, like all of the regulations in Part 440, is a coverage regulation that sets forth the services that must or may be covered by the states, and which will be eligible for federal financial participation. None of the regulations in Part 440 specify or otherwise address how states must structure their payment methodologies to reimburse for the services in question. Instead, states have flexibility to design the method or methods to pay for the services covered under the State Plan, for example on the basis of reasonable costs, fee screens, or under a prospective payment system. CMS' attempt in the proposed rule to graft a payment limitation on a coverage rule, by stating that only certain services can be covered and reimbursed as hospital outpatient services, is illogical and inappropriate.

The rule would significantly curtail the flexibility currently granted to the states. In 1987, CMS amended the definition of hospital outpatient services to add current 42 C.F.R. § 440.20(a)(4), which permits Medicaid agencies to 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. At the time it promulgated Section 440.20(a)(4), CMS stated that this revision was intended to provide states with greater flexibility to exclude any optional services

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[13] 67 Fed. Reg. 49982, 50083 (Aug. 1, 2002) (emphasis added).

that are not generally furnished by most hospitals in the state, and that this determination would be left to the states.[14] The proposed rule, which would restrict, rather than enhance, the flexibility granted to the states, is contrary to CMS' previous actions. Furthermore, it is unclear what purpose Section 440.20(a)(4) would serve if the proposed rule is promulgated, as it is difficult to see which services a Medicaid program could exclude under this provision.

Under the proposed revision, Medicaid hospital outpatient services would be limited to those services which "are not covered under the scope of another Medical Assistance service category under the State Plan." Although the meaning of this provision is not entirely clear, it appears to indicate that a state could not pay a higher rate that is reflective of services rendered by a hospital if the services also happen to fall within another service category under the state's Medicaid program. CMS' position that the services are "identical" is without merit and disregards a state's determination that the rate is appropriate for a particular provider type or setting in which the services were provided.

Services provided in hospital outpatient settings are not necessarily identical to services provided in other locations. Hospitals, particularly public hospitals, provide a broader range of services than other providers, and are essential in ensuring that services are available to the Medicaid population at least to the same extent that they are available to the general population. It is appropriate for states to make higher payments to hospitals to reimburse them for their higher costs and to encourage them to make a wide variety of services available.[15]

In California, physician services provided in hospital outpatient departments are treated as hospital outpatient services, for which the hospital receives rates that reflect an additional component for facility costs in conjunction with the rate for professional services. Additionally, many public hospitals in the State operate outpatient clinics that do not satisfy the Medicare provider-based requirements but are currently recognized by the state as provider-based under the applicable state Medicaid payment provisions. These outpatient clinics meet all of the State's licensing requirements as components of the acute care hospital, and receive Medicaid reimbursement for outpatient hospital services. The application of the Medicare provider-based rules would create payment inequities as these providers would not be appropriately compensated for furnishing outpatient hospital services, resulting in potential service reductions and restricting access to vulnerable patient populations. To the extent CMS' proposal would prohibit these types of payment methodologies, it would limit states' flexibility to make payments under their programs that best promote the provision of services to their Medicaid population.

It is a fundamental principle of administrative law that an agency must provide a reasoned basis for its action consistent with applicable law. Hospitals have relied on the payments received under the current regulation, and CMS has not provided a valid reason for the proposed change that takes into consideration its impact on payments. Accordingly, the rule should be withdrawn.

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[14] 48 Fed. Reg. 10378, 10380 (Mar. 11, 1983) (notice of proposed rule); 52 Fed. Reg. 47926, 47930 (Dec. 17, 1987) (notice of final rule).

[15] 42 U.S.C. 1396a(a)(30)(A).

C. The Rule Will Restrict Disproportionate Share Hospital Payments.

CMS cites the Louisiana Department of Health and Hospitals case to illustrate the need for "clarification" of the outpatient services definition. However, CMS makes no mention of any impact the rule will have on DSH payments, even though the core issue in that case was CMS' narrow application of the definition of hospital outpatient services to limit what the state could pay DSH facilities under the hospital-specific OBRA 1993 limit. The court in that case ruled that the uncompensated care costs incurred by hospital-based rural health centers (which were on the hospitals' licenses) with respect to uninsured patients appropriately were included as hospital costs for purposes of determining DSH payments. The court found the narrower definition CMS attempted to apply was inappropriate and contrary to congressional intent. The proposed rule change, applied in the context of the OBRA 1993 limit, would effectuate the restriction on DSH payments that was rejected by the court.

CMS' current attempt to narrow the scope of services to which DSH payments can be applied is contrary to congressional intent. The notion of "traditional" outpatient hospital services was not contemplated by Congress in the DSH context; rather, the legislative history shows that Congress intended otherwise, particularly with respect to public hospitals. Congress enacted the DSH requirement to ensure that inpatient hospital rates take into account the special costs of hospitals whose patient populations are "disproportionally composed of individuals who are either provided medical assistance under the State plan, or who have no source of third-party payment for such services." In doing so, Congress expressly recognized the broad range of services provided by public hospitals:

> Such hospitals, especially in urban areas, are often *multi-faceted* health care institutions, which provide many public health and social services to all residents of their area, in addition to serving as hospitals of last resort for the poor. Their sizable Medicaid populations often require extra social and public health services. In addition, in many areas such hospitals also provide considerable care for indigent persons not eligible for Medicaid, who often have only partial or no health care coverage. Nor do many such hospitals collect more than a small proportion of their overall revenues from non-public sources. . . . The Committee is also concerned that hospitals with large outpatient departments be reimbursed at levels for inpatient care that permit active participation in the Medicaid program and will encourage continuity of care in the treatment of Medicaid beneficiaries.[16]

Thus, Congress clearly contemplated that DSH payments would support the comprehensive range of services provided by public hospital systems, and that, as a policy matter, doing so would assure access and availability of services for Medicaid beneficiaries.

Consistent with this earlier legislative intent, the federal statute establishing the OBRA 1993 limit uses the general term "hospital services" with respect to the "costs incurred"

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[16] OBRA 1981, Energy & Commerce Comm., Report of the Committee on the Budget, H.R. Rep. No. 158, Vol. II, 97th Cong., 1st Sess., pp. 295-296 (emphasis added).

by DSH facilities.[17] It does not exclude the uncompensated costs of physician services, or services provided by hospital-based federally qualified health centers ("FQHCs"). There is no requirement that the uncompensated services, particularly those rendered to the uninsured, belong to a mutually exclusive category of services described within the state plan, nor is there any reference to the Medicare scope of outpatient services.

The proposed rule change, if applied by CMS to limit which hospital services could be recognized in determining uncompensated care costs for DSH purposes, including the OBRA 1993 limit, would deprive hospitals of substantial costs for which DSH funds could be available. Among the major categories of uncompensated hospital services that no longer would be recognized are physician services, home health services, physical, speech and occupational therapy services, services provided by hospital-based FQHCs, and services provided by outpatient and clinic components of the hospital that are recognized as hospital-based under state law, but not for Medicare payment purposes. Public hospitals would be particularly hard hit, because they provide a wide range of services out of necessity to serve their disadvantaged populations. These safety net providers rely heavily on DSH payments that are made in recognition of these hospital services.

Several California public hospitals operate hospital-based FQHCs. These are typically hospital outpatient departments or other hospital-based clinics, which are part of a provider network that receives Section 330 grant funding under the Health Care for the Homeless program.[18] Under this particular grant, clinics can receive waivers of the various governance requirements that may otherwise preclude the clinics from satisfying the Medicare provider-based criteria.[19] These clinics qualify as FQHCs, and receive payment for Medicaid covered services under the Medicaid State Plan FQHC payment methodology.[20] The uncompensated care costs incurred by these hospital-based FQHCs that are associated with services to the uninsured appropriately are recognized for DSH payment purposes, including the calculation of the OBRA 1993 limits. CMS cites no policy reason for why the outpatient hospital services provided to the *uninsured* must be mutually exclusive of other Medicaid service categories.

Similarly, out of necessity, some California public hospitals operate clinics that are recognized as hospital-based under the state's licensing laws. As discussed above, these clinics are essential to ensuring accessible care to Medicaid and other low-income populations. Consistent with current law, the state has recognized these clinics as hospital outpatient clinics, and has reimbursed them accordingly under the State Plan, even though for Medicare purposes these clinics are not reimbursed as provider-based. The uncompensated care costs incurred by these hospital clinics for services to the uninsured are appropriately recognized for DSH payment purposes.

With respect to physician services, we note that, effective July 1, 2005, California's State Plan methodology for DSH was substantially modified in conjunction with a five year Section 1115 demonstration project. Among other things, physician costs are no longer included for DSH payment purposes. However, the uninsured uncompensated care costs for public hospitals that are "lost" under the new DSH methodology currently are being recognized

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[17] Soc. Sec. Act § 1923(g)(1)(A); 42 U.S.C. § 1396r-4(g)(1)(A).
[18] Pub. Health Ser. Act § 330(h); 42 U.S.C. § 254b(h).
[19] Pub. Health Ser. Act § 330(k)(3)(H); 42 U.S.C. § 254b(k)(3)(H).
[20] Soc. Sec. Act § 1905(l)(2)(B); 42 U.S.C. § 1396d(l).

under a safety net funding pool distribution established by the demonstration. Though California voluntarily made these modifications as a condition of the demonstration, the hospitals expect and need these costs to continue to be funded, by DSH payments or otherwise, when the demonstration term ends. The proposed rule will therefore significantly impact California public hospitals.

As discussed above, CMS' revised definition of outpatient hospital services is not long-standing policy. The preamble itself notes that the current definition is very broad, which can overlap with other service categories, except to the extent that the outpatient hospital services are provided by hospitals, *i.e.*, in the hospital's licensed facilities or by its licensed sub-providers. It is a definition that has existed since nearly the inception of the Medicaid program, and Congress is presumed to act with contextual knowledge of existing regulation and policy. The interpretation reflected in the proposed rule did not exist at the time the DSH payment requirements were enacted, or when the OBRA 1993 limits were imposed. CMS provides no justification as to why the rule change is warranted for DSH purposes.

D. The Calculation Methodology For The Upper Payment Limit Is Flawed.

The UPL currently in place restricts Medicaid payments to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles.[21] The proposed rule purports to retain this limit for privately operated facilities, and, as structured, the changes to the rule assume that the cost limit provisions applicable to governmentally operated facilities are in effect. If, however, the cost limit rule is subject to further delay by Congress or is otherwise not implemented, governmentally operated facilities could be subject to the same UPL calculations set forth in the rule for privately operated facilities. This would result because under current Section 447.321(b)(1), the aggregate Medicaid payments to any of the categories of hospitals may not exceed the UPL described in Section 447.321(b)(1), which is the subject of this rule change.

The proposed rule sets forth two methodologies for states to determine the upper payment limit, both of which rely on Medicare and Medicaid charge ratios. One methodology involves a calculation of the estimated Medicare cost of the services in question, while the other methodology involves an estimate of the Medicare payment amount for the services. These methodologies contain significant flaws.

One flaw is the exclusion of the costs and payments for interns and residents from the Medicare charge and payment data. This exclusion will understate the estimated amount that Medicare would pay for the services. The Medicare program separately pays for the costs of interns and residents through the GME and Indirect Medical Education ("IME") payments as part of the inpatient hospital payments, but these payments also cover services provided in outpatient areas. Thus, the Medicare cost report excludes the costs of interns and residents from the cost-to-charge ratios on Worksheet C and Worksheet D, Part V of the Medicare cost report. Similarly, the Medicare payments for interns and residents are excluded from the Medicare hospital outpatient payments on Worksheet E, Part B. The exclusion of the costs of and payments for interns and residents will result in an incorrect calculation of the total Medicare cost-to-charge and payment-to-charge ratios. Furthermore, as noted above, the proposed

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[21] 42 C.F.R. § 447.321(b)(1).

methodology, which would exclude GME and IME costs, constitutes an implementation of the GME rule that is the subject of the congressional moratorium.

Second, there is a potential for mismatching under the methodologies set forth in the rule. The rule does not specify whether the charges are to be based on the date of service, date of payment, or date that the charge was submitted. Many hospitals experience substantial delays in generating all of the charges for Medicaid patients due to the significant delays in establishing eligibility. In California, there are frequently long delays in obtaining Medi-Cal eligibility determinations, especially for disabled persons. Furthermore, many outpatient hospital services require approval through a Treatment Authorization Request ("TAR") before they can be billed, and there are often significant delays in obtain TAR approval of the service. As a result of these and other factors, there are substantial delays in identifying the actual Medicaid charges. Thus, the UPL could be understated because it is determined using incomplete Medicaid data. It is unclear whether a state will be allowed to update the UPL using more complete data for the period at issue. CMS should clarify the charges to be used in calculation, specify whether there will be reconciliations of such charges, and ensure that there is appropriate matching of the UPL to Medicaid charges and payments.

The proposed methodologies also do not take into account the alternative charge structures that have been allowed by Medicare. For example, some hospitals use an all-inclusive charge system, whereby separate charges are not assigned to each service or item provided during an outpatient visit. Instead, each outpatient visit, and most of the ancillary care associated with the visit, is assigned to one of several different service levels based on the general quantity of services provided or the nature of the department or clinic in which the visit occurred. Thus, hospitals using all-inclusive rate structures do not maintain the level of charge detail that is typically used for cost apportionment. In these cases, hospitals have been permitted to complete their Medicare cost reports by using alternative statistics, such as relative value units ("RVUs"), instead of charges. CMS should expressly permit hospitals with alternative charge structures to utilize an alternative system for the upper payment limit calculation, instead of the cost-to-charge or payment-to-charge methodologies set forth in the rule.

The substantial flaws in the proposed methodologies require immediate attention by CMS and additional input from the states and hospitals, before any changes can be implemented. Additionally, CMS should confirm in the final rule that these methodologies will not apply to governmentally operated facilities, and that payments to these facilities will continue to be governed by the standards that were in effect prior to this rule change.

III. Regulatory Impact Statement.

CMS has determined that no regulatory impact analysis ("RIA") is necessary under Executive Order (E.O.) 12866. To justify this determination, CMS states that an RIA must be performed if the impact of a proposed rule would reach $100 million in any year, and then states that the impact of the proposal would not reach that threshold.

The $100 million per year impact, however, is only one of the several grounds under E.O. 12866 when an RIA must be performed. Under E.O. 12886, an agency must also prepare an RIA even when the annual costs would be projected at less than $100 million if its proposal would, among other things, impose an "adverse, material affect on the economy, a sector of the economy, productivity, competition, jobs, . . . public health . . . state, [or] local . . . governments [or] communities." E.O. 12866 §3. In light of CMS' failure to consider and evaluate its proposal regarding these other factors, it should withdraw the rule and perform an

RIA. In particular, CMS in its RIA should address and quantify the impact that the proposed limitation on hospital outpatient services would have on the Medicaid DSH limits for governmentally operated and privately operated providers. CMS has an obligation to recognize these impacts and quantify them.

In the Regulatory Impact Statement discussion, CMS indicates that it has a lack of available data to calculate the fiscal impact of the rule, but that it does not believe the rule would have significant economic effects. It is unclear whether CMS overlooked the impact of the rule on DSH payments, or simply concluded without thorough analysis that there would be no such impact. In either case, CMS' complete silence on these critical points renders its compliance with E.O. 12886 in question.

Furthermore, outside the issue of E.O. 12886, the rulemaking notice is inadequate as a matter of law due to CMS' failure to provide the public and potentially impacted parties with accurate information regarding the likely impact of the rule. CMS presumably is relying upon some cost estimates to reach the conclusion that its proposal will have minimal impacts, yet CMS has not identified those cost estimates so that interested parties can review and provide comments on them. This is basic legal error. See Chamber of Commerce v. SEC, 443 F.3d 890, 904 (D.C. Cir. 2006). Similarly, CMS' failure to recognize the significant economic impacts discussed above makes its proposal legally defective. Id. at 905 (vacating agency rules where agency had erroneously stated in its proposal that economic impacts would be "minimal"). And more fundamentally, an agency rule that is based upon a fundamental misunderstanding of its impact would represent a quintessential failure of "reasoned decisionmaking." Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29 (1983).

CMS also ignores the burden that would be placed on states to revise their regulations concerning hospital outpatient services and possibly to revise their state Medicaid Plans. In light of the inadequate notice regarding the rule's likely impact, CMS should withdraw it.

IV. Conclusion

The proposed regulations will adversely affect the ability of CAPH members to continue to provide critically needed health services to the most needy in California. The rule would limit the state flexibility guaranteed by the Medicaid statute to establish their payment methodology. The loss of federal funding for the health care safety net in California under this rule will be detrimental to providers and the people they serve. Therefore, CAPH urges you to withdraw this proposed rule.

Sincerely,

Melissa Stafford Jones

Melissa Stafford Jones
President & CEO

7

HCA Ventura County Health Care Agency

MICHAEL POWERS
Health Care Agency Director
Ventura County Medical Center Administrator

Karen Davis, MBA
HCA Deputy Director
Managed Health Care Director

Linda Henderson
Public Health Director

Paul E. Lorenz
HCA Deputy Director
VCMC Ambulatory Care Administrator
VCMC Compliance Officer

Ronald L. O'Halloran, MD
Medical Examiner/Coroner

Catherine Rodriguez
HCA Deputy Director
Chief Financial Officer

Meloney Roy
Acting Behavioral Health Director

Kirk E. Watson
HCA Deputy Director
VCMC Hospital Administrator

VIA FEDERAL EXPRESS

Kerry N. Weems, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2213-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Re: Comments on Proposed Rule 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 the Ventura County Health Care Agency to urge the Centers for Medicare and Medicaid Services (CMS) to rescind the September 28, 2007, rule. The proposed rule modifies the definition of Medicaid outpatient hospital services for both coverage and payment purposes, and makes revisions to the upper payment limit for outpatient hospital and clinic services.

The County of Ventura, California, owns and operates the Ventura County Medical Center (VCMC), which is a member of the California Association of Public Hospitals and Health Systems (CAPH). We share the concerns raised by CAPH in its comments to the proposed rule, and would like to set forth more particularly how the proposed rule will impact VCMC.

VCMC is part of a comprehensive health care safety net system operated by the County, which provides access to all county residents, including the uninsured, which is required under California Welfare and Institutions Code sections 17000 et seq. It is the only disproportionate share hospital system in the county, which consists of two hospital campuses, three urgent care centers and 25 ambulatory care clinic sites (primary and specialty care). Each of the ambulatory care clinics and urgent care centers are licensed under State licensing laws as components of the VCMC general acute care hospital facility. The services provided by the clinics and urgent care centers to Medicaid beneficiaries are recognized and reimbursed as outpatient hospital services under the State Plan and the State's Medi-Cal laws. Five of these outpatient hospital facilities are also recognized and reimbursed as provider-based outpatient hospital clinics under Medicare, while the remaining 23 are not. **The proposed rule, if implemented, would reduce Medicaid payments to these hospital clinics in the amount of approximately $9 million.**

2323 Knoll Drive ■ Ventura, California 93003 ■ (805) 677-5110 ■ FAX: (805) 677-5116
www.vchca.org

The County of Ventura is comprised of a population of more than 815,000. According to the 2001/2003 CHIS, there are 349,046 persons between the ages of 0-64 years (42.8% of the population) in Ventura County that are at or below 300% Federal Poverty Level (FPL). The estimated number of uninsured among this population is 86,912 persons (24.9%).

Table 1: Ventura County Uninsured under 300% FPL, Non-Elderly (ages 0-64)

Poverty Level	Estimated Population Ventura County	Est. Uninsured Ventura County	Percent Uninsured Ventura County	Percent Uninsured California
0-99%	90,752	31,400	34.6%	29.2%
100-199%	181,504	40,657	22.4%	26.3%
200-299%	76,790	15,051	19.6%	17.1%
Total <300%	349,046	86,912*	24.9%	24.9%

Source: California Health Interview Survey 2001, 2003 and California Department of Finance 2006
****Total uninsured unequal to totals by category due to rounding***

The VCMC system is structured as a community-based model to enable easier access for the target population. The hub of the system are the two hospital campuses, located in Ventura and Santa Paula. VCMC Ventura is a 180-bed general acute care hospital facility and a 43-bed psychiatric inpatient unit. VCMC Ventura maintains an active obstetric unit, with more than 3,500 deliveries per year. VCMC Santa Paula is a 49-bed general acute care hospital facility located near a large unincorporated area of the county where many low-income agricultural workers reside. Both hospital campuses offer emergency, intensive care, surgical, obstetric, and pediatric services. VCMC's 24/7 emergency rooms are staffed by board certified physicians and are base stations for paramedic services. The three urgent care centers also provide services during the day and evening when ambulatory care clinics may not be open.

Annually, VCMC provides more than 350,000 outpatient visits and close to 60,000 inpatient service days (approximately 100,000 equivalent patient days) through the inpatient and outpatient systems. More than 78% of the care provided by the system is for the safety-net population (uninsured, underinsured, Medicaid), with the remainder of the service population being 14% Medicare and 8% insured/other. During the 2005-06 state fiscal year, approximately 20,000 uninsured individuals were served. Access to outpatient hospital care via the urgent care centers and ambulatory care clinics have been essential in providing for the health care needs of the population and in managing the emergency care resources of the hospital; over a 20 year period ending in state fiscal year 2005-06, outpatient visits grew from just under 100,000 visits to more than 350,000, while emergency room visits actually declined from approximately 60,000 visits to under 41,000.

The proposed rule would, among other things, modify the definition of outpatient hospital services to require that a facility meet the Medicare criteria for provider-based status. This change, and CMS' intent to apply this definition to state rate making, goes beyond a mere "clarification" and would substantially reduce Medicaid payments to VCMC.

Under current Medicaid law, California exercised its flexibility to establish rates that recognize licensed outpatient components of acute care hospitals as outpatient hospital

clinics without regard to a facility's provider-based status under Medicare. Different payment levels apply to services rendered by outpatient hospital clinics versus services rendered by other provider types. For example, the physician and other professional services rendered at these clinics are reimbursed as outpatient hospital services which include, in addition to the professional fee, a hospital facility payment. Government owned and operated outpatient hospital facilities also receive supplemental Medicaid payments for the otherwise uncompensated costs of rendering services to Medicaid beneficiaries, which are certified as public expenditures. For state fiscal year 2004-05, these payments totaled $ 7,736,688 for VCMC's outpatient hospital clinics.

The proposed application of the Medicare provider-based requirements would reverse the longstanding status of VCMC's outpatient hospital clinics under the State's Medicaid program. Notwithstanding Medicare's provider-based rules, which were established specifically for the Medicare outpatient payment methodology, California's licensing laws recognize all of VCMC's outpatient clinics as components of the hospital. The clinic locations and management model are particularly well suited for the special needs of County residents. This is why their services are critical to the State's Medicaid program in providing access to care for beneficiaries. The State's Medicaid reimbursement structure appropriately recognizes the services provided by the VCMC clinics as outpatient hospital services, and pays rates that are commensurate with those services. The proposed rule would strip VCMC of essential outpatient hospital services payments currently provided for under the State Plan.

Moreover, the proposed rule would have an impact on VCMC's ability to receive disproportionate share hospital (DSH) payments. As noted above, VCMC is the only DSH facility in the County. If the revised definition is applied by CMS with respect to the determination of DSH payments, including the OBRA 1993 limits, then the uncompensated costs of care rendered to the uninsured by VCMC's clinics would be excluded. In state fiscal year 2004-05, VCMC's clinics incurred more than $ 28,061,382 in uncompensated care costs associated with uninsured patients. We do not see any rational basis to support this result. In fact, CMS does not even acknowledge in the preamble that there is a DSH impact.

Given the substantial change being made by the proposed rule, its effect on payments and the particular financial impact on VCMC, and CMS' failure to address these financial impacts, we urge you to withdraw this proposed rule.

Sincerely,

Michael Powers
Director
Ventura County Health Care Agency

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children's
MEDICAL CENTER

10/26/07

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 our community served by Medicaid, Children's Medical Center Dallas 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.* Children's Medical Center Dallas is a major provider of outpatient services for children in Texas insured by Medicaid. The proposed regulatory changes would have a negative impact on our hospital and the children we serve.

We urge CMS not to implement the rule for two reasons. First, Congress' moratorium on implementation of changes to state financing mechanisms and graduate medical education payments under Medicaid deny CMS the authority to implement the rule as currently drafted. Second, The National Association of Public Hospitals has done a detailed analysis of the proposed regulation on outpatient hospital services and found that the regulation violates the 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.

We also urge CMS not to implement the rule for several additional reasons:

The Proposed Rule Overlooks Critical Outpatient Hospital Services for Children
We understand that CMS is trying to provide more clarity on what is and what is not a Medicaid outpatient hospital service, but the narrow Medicare definition included in the proposed regulation does not reflect the reality of the Medicaid program today and the significant role it plays for children. More than one-fourth of all children are insured by Medicaid and over 50 percent of Medicaid beneficiaries are children.

1935 Motor Street Dallas, Texas 75235
tel | 214.456.7000 web | www.childrens.com

The Medicare definition for outpatient services is inappropriate for children because it was not developed to address their unique health care needs. 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 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; currently, Children's Medical Center Dallas conducts more than 300,000 outpatient visits per year. Forty-six percent of outpatient visits excluding the ER at Children's Medical Center Dallas are children insured by Medicaid. Also, forty-six percent represents the Gross Charges Children's Medical Center Dallas bills from Medicaid patients. Most children's hospitals provide a full range of outpatient services to children insured by Medicaid. CMCD has more than 50 outpatient clinics with the Children's Pavilion allowing most of the hospital's outpatient services to operate in one location. CMCD also has outpatient specialty center offering multi-specialty outpatient services in one conveniently located, patient-friendly site for families in the Collin, Denton, Fannin, Grayson and Cooke county areas. The Legacy Pavilion, located in Collin County offers services by members of the Children's medical/dental staff who also are UT Southwestern faculty members including: Asthma, Behavioral Health, Cardiology, EKG, Echocardiography, Endocrinology, Gastroenterology, Hematology, Laboratory Services, Nephrology, Nutrition, Occupational Therapy, Ophthalmology, Physical Therapy, Plastic Hand Surgery, Plastic Surgery/Craniofacial, Pulmonary Function Testing, Pulmonology, Radiology, Speech Therapy, and Urology.

The changes in the outpatient hospital services definition would have a negative impact on our hospital. 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 taking services out of the definition, CMS would be lowering reimbursement for these important services that our hospital provides to children insured by Medicaid. This reduction would exacerbate the inadequate Medicaid outpatient reimbursement our hospital receives, which already falls substantially below the cost of care we provide.

Our hospital is a major provider of outpatient care to children assisted by Medicaid. Currently, our state Medicaid program reimburses our patient care only fifty-one percent of the cost of care. We cannot afford to absorb additional Medicaid payment shortfalls without jeopardizing the hospital's ability to sustain the full scope of outpatient services we currently provided.

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 a smaller payment for my hospital. As a safety net hospital, DSH payments are vital to our ability to care for all children.

CMS Is Unable to Estimate Impact of the Proposed Rule

Due to lack of data, CMS says it is unable to estimate the impact of the proposed regulation. This is extremely troubling for my hospital. Before a regulation of this magnitude is implemented, the impact should be specified and addressed. CMS does not address the potential effect on children and children's providers of adopting a Medicare service definition. This change could impact the services hospitals are able to provide for children and therefore children's access to outpatient hospital services. CMS should explore the potential effects of these changes and any revisions needed to continue to provide quality and accessible health care services for children.

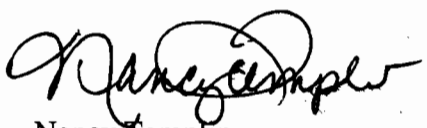
Conclusion

As you can see from our comments, we are extremely concerned about this proposed regulation and the impact it would have on children enrolled in Medicaid and on children's hospitals. 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 and would be pleased to discuss them further. For additional information, please contact Julia Easley at 214-456-5342 or Julia.easley@childrens.com.

Thank you for your consideration.

Sincerely,



Nancy Templin
Chief Accounting Officer

St. Helena Parish Hospital

"Louisiana's First Critical Access Hospital"

October 25, 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:

We are writing to object to the outpatient clinic and hospital services facility services definition proposed rule that was published in the Federal Register on September 28, 2007. Your reference is CMS-2213-P--Outpatient clinic and hospital services facility services definition.

We are a small rural hospital located in Greensburg, Louisiana, with a hospital-based rural health clinic (RHC) that functions as part of the hospital. The hospital employs the RHC's personnel, pays its bills, performs quality assurance, credentials the physicians and physician assistants employed by the RHC, owns / leases 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 will limit our hospital's ability to provide services at the RHC, because disproportionate share funding covers much of the cost of the RHC's services. This will limit our ability to provide care to those who need it most and are unable to pay for it. 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.

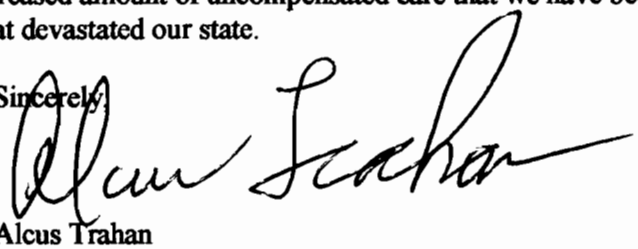
Such improper use of the emergency department by indigent patients strained our hospital's limited resources. It also makes it difficult for those patients to get timely care. Our hospital-based RHC solved this problem by giving those patients a less expensive and readily-

available alternative to the emergency room. This 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.

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 proposed definition will have a severe financial impact on our hospital, which will further limit our ability to provide the increased amount of uncompensated care that we have been asked to provide after the 2005 storms that devastated our state.

Sincerely,



Alcus Trahan
Administrator/CEO

AT:sb

Memorial
HEALTH
University Medical Center

October 26, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS –2213– P
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 (*Federal Register* / Vol. 72, No. 188, September 28, 2007, pages 55158-55166).

Dear Acting Administrator Weems:

Thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule concerning the Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit. Memorial Health University Medical Center (MHUMC) is a 530-bed teaching hospital with one of only four Level I Trauma Centers in the State of Georgia.

The purpose of the proposed rule is to clarify the definition of the benefit for "outpatient hospital services" under section 1905(a)(2)(A) of the Act, and the application of that definition under the applicable Upper Payment Limit (UPL). This rule proposes to describe the scope of services States may include in the outpatient hospital UPL and define appropriate Medicare references that States must use when calculating the UPL for Medicaid outpatient hospital services. The rule proposes to align the Medicaid definition of outpatient services with the Medicare definition of outpatient services and clarify Medicaid's corresponding UPLs for outpatient hospital and clinic services.

The Proposed Rule is significant because it both narrows the regulatory definition of outpatient hospital services, and adopts restrictive and mandatory approaches to calculating the UPL for outpatient hospital and clinic services provided by private providers. Although the total magnitude of the impact of the proposed changes is unclear, the Proposed Rule will result in lower payments for hospitals, both because some services would no longer be reimbursable as outpatient hospital services and because some services could no longer be included in calculating the outpatient hospital UPL. While the UPL provisions of the Proposed Rule purport to apply only to private providers, the provisions are significant for governmental providers as well. The Proposed Rule allows states to use costs as an acceptable UPL for private hospitals, and in doing so, provides much more detail than previously on acceptable methodologies for determining costs, methodologies that would likely be used in applying any cost limit to governmental entities as well.

Specifically, in dictating the specific sections of the Medicare cost report that a State may use in calculating information for the outpatient UPL, this proposed rule effectively excludes Graduate Medical Education (GME) costs from the outpatient costs that a State can include. The preamble explicitly references the "cost-to-charge ratios as found on Worksheet C, Column 9 of the CMS 2552-96." These ratios are calculated using information from Worksheet B, Column 27 – which explicitly excludes all costs related to interns and residents. Furthermore, CMS goes on in the same paragraph to state that "CMS will not accept a UPL that is inflated by adjusting Medicare's allowed cost as reported on these worksheets." CMS also explains in the preamble that it believes this proposed rule is a clarification of the existing definition of hospital outpatient services and would have a minimal

estimated impact. Therefore, CMS believes that this proposal does not reach the threshold to be categorized as a "major rule" and can take effect whenever specified by the Agency once it is properly finalized. It is not clear as to what the exact effect will be on UPL payments hospitals, but it is clear that the exclusion of Medical Education costs will from that calculation will result in a significant reduction in UPL payments to teaching hospitals.

This proposed rule would also have an indirect impact on disproportionate share hospital (DSH) reimbursement for private and governmental hospitals alike, although this aspect of the proposal is not acknowledged by CMS. To the extent that the new, narrow definition of outpatient hospital services excludes services a state is currently treating as outpatient services, the uncompensated care costs associated with those services would no longer be includable in a hospital's DSH cap. This would be another significant reduction to teaching hospitals. DSH funding that would have gone to teaching hospitals will now be redirected to non-teaching hospitals. This is another devastating hit for teaching hospitals.

MHUMC believes that this proposal is in direct violation of the moratorium enacted by Congress prohibiting implementation of the Medicaid cost limit rule and changes to graduate medical education policy. In particular, the Proposed Rule contains regulatory language that is part of the final cost limit rule that CMS is barred from implementing. The Proposed Rule also effectively prohibits States from including outpatient GME costs in private hospital outpatient reimbursement in direct violation of the prohibition on modifying GME policy. The language of the Moratorium prohibits CMS from "taking any action (through promulgation of regulation) to finalize or to otherwise implement provision contained in the Cost Limit Rule. In issuing the Proposed Rule, CMS is again attempting to remove facility ownership from consideration in applying the outpatient UPL, a change that is clearly within scope of the prohibition adopted by Congress in the Moratorium.

The Proposed Rule also effectively prohibits states from including GME costs in the outpatient UPL, thereby narrowing States' flexibility to support GME and again violating the Moratorium. The language of the moratorium prohibits CMS from "taking any action (through promulgation of regulation, issuance of regulatory guidance, or other administrative action) to promulgate or implement any rule or provisions restricting payments for graduate medical education under the Medicaid program." The new detailed requirements of this proposal for calculating cost for purposes of the outpatient hospital UPL reduces the ability of States to make payments to GME by excluding GME costs from those that may be included. This result is in clear conflict with the language of the moratorium prohibiting the promulgation of regulation restricting payments for Medicaid GME.

Although characterized by CMS as a "clarification," the reality is that the proposed rule represents a major reversal of long-standing Medicaid policy. For decades, most State Medicaid programs have supported the higher costs of teaching hospitals. CMS and its predecessor, the Health Care Financing Administration, have approved and matched these payments. This proposed clarification would exclude medical education costs that are appropriately allocated to outpatient departments of our hospital. This eliminates nearly 1 million dollars in Medicaid Medical Education Reimbursement. Teaching hospitals rely on these and other Medicaid payments to support our critical functions.

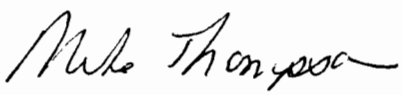
Medicaid GME payments help teaching hospitals sustain one of our core responsibilities: providing the clinical education of future physicians. Within a supervised patient care team of health care professionals, medical residents provide needed care to Medicare, Medicaid, and other patients as part of their training programs. Educating future physicians and other health care professionals has never been more important given the numerous studies predicting a physician shortage in the near future. As the region's only Teaching Hospital, we provide the medical education experience for more than 100 residents in 6 different programs: Internal Medicine, Family Practice, Pediatrics, Surgery, OB/GYN, and Radiology. AAMC has called for existing medical schools to increase their residency enrollment by 30% in order to avoid the physician shortages predicted in the near future. Funding for graduate medical education will be necessary in order to train these additional graduates. MHUMC has already reached its allowable Resident FTE Cap. This means that no additional funding is available for any future increases to our number of graduate medical education slots. If this proposed clarification is adopted, MHUMC will haven no choice but to make significant changes in our resident positions to balance the loss in funding. As the only academic medical center within a 200-mile radius, I believe we have a responsibility to the citizens of our city, region, and state to graduate competent physicians to meet their future healthcare needs. However, our greater responsibility is to meet our region's immediate healthcare needs. If this proposed rule is adopted, MHUMC will be forced to make

some very difficult choices. Excluding medical education costs from the Outpatient Hospital Services definition significantly reduces FFP for State Medicaid agency payments for GME at a time when more physicians are needed throughout the country is not in our Nation's best interest.

Because half of all Medicaid discharges are from the nation's nearly 1100 teaching hospitals, GME funding cuts of any kind could also affect other services offered to Medicaid and other patients by reducing teaching hospitals' total financial resources. Teaching hospitals provide an environment in which clinical research can flourish and where highly specialized tertiary patient care such as burn care, trauma and cardiac care, and transplant services take place. Because of their education and research mission, teaching hospitals offer the most advanced, state-of-the-art services and equipment, and with residents and supervising physicians available around-the-clock, teaching hospitals care for the nation's sickest patients. Most recently, teaching hospitals are looked to as front-line responders in the event of a biological, chemical, or nuclear attack and are implementing plans to fulfill that role.

Memorial Health University Medical Center respectfully requests that you reconsider and rescind this proposal. Once again, thank you for considering our remarks on the proposed rule. If you have any questions about our comments, please feel free to contact me.

Sincerely,



Mike Thompson
Manager of Reimbursement, MHUMC

Cc: Bob Colvin, President and CEO, MHUMC
Maggie Gill, COO, MHUMC
Darcy Davis, Vice President of Finance, MHUMC
Ramon Meguiar, Chief Medical Officer, MHUMC
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North Carolina Hospital Association

October 26, 2007

Mr. Kerry N. Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Ave, SW
Washington, DC 20201

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:

On behalf of North Carolina's 100 acute care hospitals, we appreciate the opportunity to comment on the Centers for Medicare and Medicaid Services proposed rule changing Medicaid policy for federal reimbursement of Medicaid hospital outpatient services. This is a significant rule that would have a major financial impact on the hospitals that provide these vital services to the needy in our State.

This rule clearly violates Congress' moratorium which prohibits CMS from implementing and/or issuing regulations that relate to (a) new definitions of what constitutes hospitals that are "units of government" versus private and (b) restrictions on Medicaid funding for Graduate Medical Education.

First, CMS is proposing changes to the hospital outpatient upper payment limit methodology by adopting the same definitions for the categories of providers that are subject to the upper payment limits (UPLs) that appear in the regulations and are subject to the moratorium. Second, the proposed rule does not permit state Medicaid programs to count GME costs in determining the outpatient UPL, again violating the moratorium barring any regulatory activity on restricting GME payments made.

The North Carolina Hospital Association opposes these proposed regulations and urges CMS to immediately and permanently withdraw them. If these policy changes are implemented, the State's health care safety net will again be adversely impacted, causing health care services for thousands of our State's most vulnerable people to be jeopardized.

If you have questions about these comments, please call me at 919/677-4217.

Sincerely,

Millie R. Harding

Millie R. Harding
Senior Vice President

MHA

October 26, 2007

Kerry Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

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 Maine Hospital Association appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule changing Medicaid policy for federal reimbursement of Medicaid hospital outpatient services. The Maine Hospital Association represents all of Maine's 39 acute care and specialty hospitals and their affiliates. All of our acute care hospitals are nonprofit, community-governed organizations. Maine is one of only a handful of states in which all of its acute care hospitals are non-profit.

In the Federal Register issued on September 28, 2007, CMS describes the Medicaid hospital outpatient proposed policy changes as clarifications to current rules. CMS further states that because these changes will not result in a significant financial impact, the proposed rule is not considered a major rule and, therefore, a 30-day comment period is sufficient. The Maine Hospital Association disagrees with all of these points, especially because we believe the change in the definition of hospital outpatient services will cause our hospitals to lose tens of millions of dollars in Medicaid reimbursement for outpatient hospital services. The change will also force patients to look for these services outside of the hospital in areas where the services simply don't exist in our small and rural state.

Furthermore, this proposed rule is making major policy changes to the Medicaid program therefore a 30-day comment period is insufficient for public comment. CMS is also violating the Congressional moratorium barring the agency from regulating matters pertaining to how states finance their Medicaid programs and fund graduate medical education (GME) payments. The Maine Hospital Association strongly opposes these changes and urges CMS to withdraw this rule.

Definition of Hospital Outpatient Services

The proposed rule repeals the long-standing definition of Medicaid outpatient hospital services and replaces it with new and much more narrow definition. CMS bases this dramatic shift in policy on the desire to align Medicaid outpatient policies with Medicare outpatient polices. This is not appropriate because these programs serve very different populations. For example, Medicaid serves a younger population with a large number of pediatric cases while Medicare serves the elderly

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population. Yet despite these differences, CMS is proposing to narrowly define Medicaid hospital outpatient services to align it with Medicare. The only justification for aligning the hospital outpatient policies for these two programs would be to limit Medicaid spending for hospital outpatient programs and limit the flexibility of state Medicaid programs.

Current Medicaid regulations broadly define allowable hospital outpatient services to include preventative, diagnostic, therapeutic, rehabilitative or palliative services provided under the direction of a physician or dentist in a hospital. Under the proposed rule, the types of services that are at risk for not being reimbursed through hospital outpatient programs include Medicaid's early and periodic screening and diagnostic treatment services for children; physical, occupational and speech therapy; outpatient clinical diagnostic laboratory services; ambulance services; durable medical equipment; outpatient audiology services; and most notably for Maine, outpatient and emergency department physician services. In many areas of Maine these services do not exist or are unavailable outside of hospital outpatient departments. This is especially true for Medicaid patients given the low reimbursement rates offered by the program to private practitioners.

CMS states in this proposal that the services no longer reimbursed through hospital outpatient departments will be paid for through other parts of the Medicaid program. This is not true in Maine and the agency would not be able to demonstrate that there is access to such services within the community outside of the hospital outpatient department in our state.

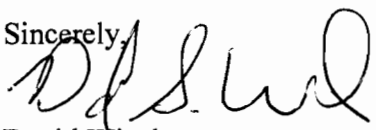
CONCLUSION

CMS states in the preamble that the fiscal impact of this rule would be minimal because the rule is a clarification of existing policy and would not result in the elimination of coverage. The Maine Hospital Association believes that the agency may have failed to properly perform the due diligence necessary to make these statements. This rule change will cost Maine hospitals tens of millions of dollars in Medicaid reimbursement. Furthermore, we would contend that these policy changes will seriously affect access to important outpatient services, especially physician services for Medicaid patients.

The Maine Hospital Association urges CMS to withdraw this rule and suspend any further regulatory activity that affects the issues encompassed under the moratorium secured by P.L. 110-28. These proposed policy changes will result in cuts to state Medicaid programs, cuts in payments to hospitals, and reduced access to needed services for potentially thousands of vulnerable people served by the Maine Medicaid program.

If you have any questions, please feel free to contact me at (207) 622-4794 or dwinslow@themha.org.

Sincerely,



David Winslow
Vice President of Financial Policy

cc: Senator Olympia Snowe
Senator Susan Collins
Representative Michael Michaud
Representative Thomas Allen