

health or safety risks, such that the analysis required under section 5–501 of the EO has the potential to influence the regulation. This action is not subject to EO 13045 because it is based solely on technology performance.

H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not subject to Executive Order 13211 (66 FR 28355 (May 22, 2001)), because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) of 1995 (Pub. L. 104–113, Section 12(d), 15 U.S.C. 272 note) directs EPA to use voluntary consensus standards (VCS) in its regulatory activities, unless to do so would be inconsistent with applicable law or otherwise impractical. The VCS are technical standards (e.g., materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by VCS bodies. The NTTAA directs EPA to provide Congress, through OMB, explanations when the EPA does not use available and applicable VCS.

This final rule does not involve technical standards. Therefore, EPA did not consider the use of any voluntary consensus standards.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order (EO) 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this final rule will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it does not affect the level of protection provided to human health or the environment. This action extends the compliance date of the rule from January 1, 2009, to July 1, 2009, and

does not relax the control measures on sources regulated by the rule.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. The EPA will submit a report containing the final rule amendment and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule amendment in the **Federal Register**. The final rule amendment is not a “major rule” as defined by 5 U.S.C. 804(2). This final rule is effective on December 29, 2008.

List of Subjects in 40 CFR Part 59

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements.

Dated: October 30, 2008.

Stephen L. Johnson,
Administrator.

■ For the reasons set out in the preamble, title 40, Chapter I of the Code of Federal Regulations is amended as follows:

PART 59—[AMENDED]

■ 1. The authority citation for part 59 continues to read as follows:

Authority: 42 U.S.C. 7414 and 7511b(e).

Subpart E—[Amended]

■ 2. Section 59.501 is amended by revising the first sentence of paragraph (c) and the first sentence of paragraph (f)(3)(i) to read as follows:

§ 59.501 Am I subject to this subpart?

* * * * *

(c) Except as provided in paragraph (e) of this section, the provisions of this subpart apply to aerosol coatings manufactured on or after July 1, 2009, for sale or distribution in the United States. * * *

* * * * *

(f) * * *

(3) * * *

(i) You must submit an initial notification no later than the compliance date stated in § 59.502(a), or on or before the date that you start manufacturing aerosol coating products

that are sold in the United States, whichever is later.

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■ 3. Section 59.502 is amended by revising paragraph (a) to read as follows:

§ 59.502 When do I have to comply with this subpart?

(a) Except as provided in § 59.509 and paragraphs (b) and (c) of this section, you must be in compliance with all provisions of this subpart by July 1, 2009.

* * * * *

■ 4. Section 59.511 is amended by revising the first sentence of paragraph (b) introductory text and the first sentence of paragraph (e) introductory text to read as follows:

§ 59.511 What notification and reports must I submit?

* * * * *

(b) You must submit an initial notification no later than the compliance date stated in § 59.502(a), or on or before the date that you first manufacture, distribute, or import aerosol coatings, whichever is later.

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(e) If you claim the exemption under § 59.501(e), you must submit an initial notification no later than the compliance date stated in § 59.502(a), or on or before the date that you first manufacture aerosol coatings, whichever is later. * * *

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[FR Doc. E8–26614 Filed 11–6–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS–2213–F]

RIN 0938–AO17

Medicaid Program; Clarification of Outpatient Hospital Facility (Including Outpatient Hospital Clinic) Services Definition

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: Outpatient hospital services are a mandatory part of the standard Medicaid benefit package. This final rule aligns the Medicaid definition of outpatient hospital services more

closely to the Medicare definition in order to: Improve the functionality of the applicable upper payment limits (which are based on a comparison to Medicare payments for the same services), provide more transparency in determining available hospital coverage in any State, and generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category.

DATES: *Effective Date:* These regulations are effective December 8, 2008.

FOR FURTHER INFORMATION CONTACT: Jeremy Silanskis, (410) 786-1592.

SUPPLEMENTARY INFORMATION:

I. Background

A. Definition of Outpatient Hospital Services

Section 1905(a)(2)(A) of the Social Security Act (the Act) lists outpatient hospital services as a benefit that can be covered under a State Medicaid program, and it is a mandatory benefit for most eligible Medicaid populations under sections 1902(a)(10)(A) and 1902(a)(10)(C)(iv) of the Act. Though the statute does not provide a definition for these services, federal regulations at 42 CFR 440.20 were established to define: An outpatient hospital service, the circumstances under which outpatient services are delivered, and qualifications for Medicaid outpatient hospital service providers.

As discussed in the proposed rule, the proposed changes would address ambiguity in the definition of outpatient hospital services which allowed for a high possibility of overlap between outpatient hospital facility services and other covered Medicaid benefits. CMS viewed the overlap in service definitions as problematic for several reasons. The broad definition of outpatient hospital services did not clearly limit the scope of the outpatient hospital service benefit to those services over which the outpatient hospital has oversight and control. The overlap could result in payment at the high levels customary for outpatient hospital facility services instead of at the lower levels associated with the other covered benefits. Also, the definition's ambiguity potentially allowed States to include services paid for under other Medicaid benefit categories in the State plan in the calculation for Medicaid and uncompensated care cost supplemental payments for outpatient hospital services. In addition, the definition was inconsistent with the applicable upper payment limit (UPL), which is based on the premise of some level of

comparability between the Medicare and Medicaid definitions of outpatient hospital and clinic services.

B. Calculation of Outpatient Hospital and Clinic Upper Payment Limits

Regulations at 42 CFR 447.321 define the UPLs for Medicaid outpatient hospital and clinic services. The UPLs for outpatient hospital and clinic facilities are based on the amount that would be paid under Medicare payment principles. We proposed to clarify this standard by incorporating into the regulatory text guidance concerning the methods for demonstrating compliance with the UPLs.

In consideration of the Congressional moratorium on the proposed rule on Cost Limits for Governmentally-Operated Providers (the "Government Provider Payment Rule"), published on January 18, 2007 (72 FR 2236), we are reserving action on the proposed provisions at § 447.321. We may consider publication of the UPL guidance at a future date. If the UPL guidance is published in the future, we will respond to the public comments concerning those regulatory clarifications at that time. Since this final rule only concerns changes to the outpatient hospital service definition, we have modified the title of the final regulation to read: Clarification of Outpatient Hospital Facility Services Definition.

C. Proposed Regulation

CMS published a proposed rule in the **Federal Register** on September 28, 2007 (72 FR 55158), entitled "Clarification of Outpatient Clinic and Hospital Facility Services Definition and Upper Payment Limit." We provided for a 30 day public comment period and received a total of 333 timely comments from States, local government, providers, and health care associations. Brief summaries for each proposed provision, a summary of the public comments we received, and our responses to comments, are set forth below.

II. Provisions of the Proposed Rule and Response to Comments

General Comments

Comment: A substantial number of commenters urged CMS to withdraw the proposed rule. They stated the regulatory changes are in violation with the Congressional Moratorium passed as part of the Troop Readiness, Veterans' Care, Katrina Recovery, and Iraq Accountability Appropriations Act of 2007. Nearly all of the comments concerning a violation of the moratorium focused on: The exclusion

of graduate medical education costs and payment in the outpatient upper payment limit calculation, and the inclusion of certain terminology and citations in the proposed rule that were a part of the proposed rule on Cost Limits for Governmentally-Operated Providers (the "Government Provider Payment Rule"), published on January 18, 2007 (72 FR 2236) and the proposed rule for Medicaid Graduate Medical Education (the "GME Rule") published on May 23, 2007 (72 FR 28930).

Response: The proposed rule addressed completely different policy concerns from those published in the proposed Government Provider Payments Rule and the GME Rule. Those rules concern the amount of the permissible payment for government providers or for institutions offering graduate medical education, rather than the scope of the outpatient hospital benefit.

In our proposed rule, we integrated the proposed provisions in with the provisions of the Government Provider Payment Rule because that rule had been published in final form. Integrating this proposed rule with the provisions of the Government Provider Payment Rule misstated the existing regulatory framework. We regret any concern this may have caused.

Therefore, we are reserving action on the proposed clarifications to the outpatient hospital and clinic upper payment limits at 42 CFR 447.321. We may address these provisions at a future date, at which time we will respond to the public comments we received concerning the payment limit clarifications.

Comment: A number of commenters asserted that the rule did more than clarify ambiguous regulatory language and formalize existing CMS policy. Many commenters stated that the proposed regulation was unwarranted and poor public policy. One commenter opined that "CMS has (not) adequately demonstrated the need for the proposed changes to the regulations regarding the definition of outpatient hospital services." Another commenter stated: "The proposed regulatory changes seem arbitrary, not developed with care and not fulfilling CMS's own purposes." Still, an additional commenter stated that the rule "is neither transparent nor clarifying." Many commenters stated that the rule was not a minor clarification of CMS policy.

Response: As discussed in the proposed rule, the purpose of the regulation is to establish consistency between the definition of Medicaid outpatient hospital services and the applicable upper payment limit for

those services, to provide more transparency in determining available hospital coverage in any State, and to generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category.

For example, in our review of State plan amendments, we found that one State was including numerous services defined under other Medicaid benefit categories and non-Medicaid covered services within the Medicaid outpatient hospital benefit category. Some or all of these services were provided in settings that did not involve the high overhead costs of a hospital facility. The State's apparent purpose in defining the services as part of the outpatient hospital services benefit was to include the services in the calculation of the outpatient hospital upper payment limit, in order to justify targeted supplemental payments to hospitals that would otherwise violate applicable upper payment limits.

We are concerned that such arrangements increase the outpatient hospital upper payment limit without any justification based on any increased cost or service levels, and thus is not consistent with efficient and effective management of a Medicaid program.

This regulation will clarify that such arrangements, in which higher payments are not justified by increased costs or service levels, are not permitted. Therefore, we respectfully disagree that the regulation does not provide additional clarification or that the proposed changes are arbitrary.

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

Response: The regulations at 42 CFR recognize facility services provided to outpatients in outpatient hospital and clinic setting. As of the publication of this final regulation, there are no upper payment limits for non-institutional practitioner services defined in regulation. As with any rate methodology, payments for other non-institutional services must comply with section 1902(a)(30)(A) of the Act, which requires that State plans have methods and procedures to assure that payments are consistent with economy, efficiency and quality of care. To establish such compliance, CMS may ask a State to explain a reasonable basis for its rates. Within the scope of 1902(a)(30)(A), CMS allows States to determine payment rate methodologies for non-institutional

practitioner services consistent with regulations at 42 CFR 430.10 and 447.204.

Comment: One commenter requested that CMS clarify how a State should account in its UPL calculation for mandatory outpatient hospital services that are not covered by Medicare as outpatient hospital services, or are specified in Medicaid regulations as a separate State Plan category of service. The commenter was under the impression that such services could be required outpatient hospital services pursuant to current 42 CFR 440.20(a)(4) (which would be moved to 42 CFR 440.20(a)(5) under this rule).

Response: The provisions at 42 CFR 440.20(a)(5) are generally intended to provide States with the discretion to limit the outpatient hospital service definition to exclude services that are not typically provided in hospitals within the State. We do not interpret this section of the regulation to expand the available scope of services beyond those recognized under the Medicare outpatient prospective payment system or paid by Medicare as an outpatient hospital services under an alternative payment methodology. Instead, the provision allows States to define the benefit category to exclude services that are not typically provided in hospitals within the State.

Comment: One comment supported implementing the proposal into a final regulation and offered that "using consistent definitions across these programs helps to simplify a very complex array of regulations and pricing policies."

Response: We thank the commenter for supporting the provisions of the proposed regulation.

Outpatient Hospital Service Definition

We proposed to define Medicaid outpatient hospital services at 42 CFR 440.20 to include those services recognized under the Medicare outpatient prospective payment system (defined under 42 CFR 419.2(b)) and those services paid by Medicare as an outpatient hospital service under an alternate payment methodology. Further, we have proposed to limit the definition to exclude services that are covered and reimbursed under the scope of another Medicaid service category under the Medicaid State plan and required that services be furnished by an outpatient hospital facility or a department of an outpatient hospital as described at 42 CFR 413.65.

Comment: Several commenters stated that the proposed rule eliminates hospital overhead from many hospital and ambulatory services. Further, a

number of commenters noted that the rule discourages safety net providers from providing community-based primary and preventive ambulatory care services that improve community health and reduce future health care costs.

Response: This rule would not have such effects. There is nothing in this rule that precludes States from paying for community-based primary and preventive ambulatory care services at rates that fully account for costs to provide such services. This rule would, however, provide for greater transparency in paying for such costs because the payments would be made directly on a fee-for-service basis rather than indirectly through complex facility or supplemental payment programs. As a result, it will be easier to compare the cost-effectiveness of different providers.

In other words, while this regulation would require that States distinctly reimburse hospitals for the facility expenses and separately reimburse for the practitioners who provide the Medicaid services within the facility, it would not eliminate any Medicaid benefit category, place reimbursement restrictions on those categories, or alter the qualifications that must be met to provide a Medicaid covered service. Any non-institutional Medicaid service covered under a State's plan may continue to be provided in a safety-net hospital, a clinic, or other non-institutional setting by a service practitioner who meets the provider qualifications for the service set forth in the State plan.

Further, under section 1902(a)(32) of the Act, the hospital may collect payment on behalf of the practitioner if the practitioner is required to turn over the Medicaid fee on condition of employment or a contractual arrangement.

Comment: Many commenters questioned whether the Medicare definition included in the proposed regulation considers the role of the Medicaid program in providing services to other populations. Commenters noted that the Medicare and Medicaid programs are different in both scope and the populations that they serve. In addition, the commenters pointed out that Medicare is a Federal program with national standards, whereas Medicaid is a State/Federal partnership with programmatic variations among the States. One commenter cited examples of services provided to children that are not covered under the Medicare programs, such as: Dental and vision services, annual check-ups, and immunizations. By restricting the scope of Medicaid services to those covered under Medicare, the commenter stated

that CMS would be lowering the reimbursement for these important services that hospitals provide to children insured by Medicaid, which fall below the cost of care. The commenter suggested that CMS delay implementation of the regulation and review the potential impact of the regulation on Medicaid eligible children and the providers that serve them.

Response: We believe that the difference in populations served by Medicare and Medicaid has no impact on the nature and scope of outpatient hospital facility services recognized by Medicare under OPPTS or an alternate fee schedule. We note that Medicare covers individuals under the age of 65 with disabilities and that the Medicare program recognizes procedures for a wide array of services that are not unique to individuals over age 65. We have examined the Medicare payment systems and are unable to identify hospital facility costs that are not recognized by the Medicare program that would be unique to children or other populations that are not covered under the Medicare program.

To the extent that there are such services, however, we interpret the phrase "would be included" at 42 CFR 440.20(a)(4) of this rule to include services that are not actually paid by Medicare under OPPTS or an alternate payment methodology, but that would be paid under those methodologies if furnished to a Medicare beneficiary.

This is consistent with the goal of this regulation, which is to limit the scope of Medicaid State plan outpatient facility services to the type and scope of services that are generally recognized as actual hospital services. We believe that the outpatient services described in the proposed regulation represent the full and appropriate scope of services provided in outpatient hospital settings. The services mentioned in the comments are covered under other, distinct Medicaid service definitions. These services may continue to be provided and reimbursed by Medicaid within hospital settings under the coverage policies and reimbursement methodologies defined by States specific to those services.

Comment: Several of the commenters stated that under the Medicare program, physical therapy is recognized as a separate benefit and the service providers are qualified to provide services without physician supervision. Under the Medicaid program, these commenters urged, many States exclusively offer physical therapy services within outpatient hospitals under the outpatient hospital benefit category.

Response: The proposed regulation allows for services that are not covered under another Medical Assistance benefit category under the State plan to be included as part of the outpatient hospital facility benefit if the services are recognized under the Medicare OPPTS or paid as outpatient hospital services under an alternate fee schedule. Therefore, if a State chooses to only cover and pay for these services as part of the outpatient hospital benefit and the services are recognized under the Medicare OPPTS or paid as outpatient hospital services under an alternate fee schedule, the services may be part of the outpatient hospital Medicaid definition. However, if the services are covered as a non-institutional practitioner service under a separate benefit category, the State must pay for those services under the reimbursement methodology specific to that benefit category and may not define the services in the State plan as outpatient hospital facility services. Regardless, physical therapy services may continue to be paid under the Medicaid program in outpatient hospital settings.

Comment: One commenter stated that free-standing outpatient rehabilitation facilities should be treated as outpatient hospitals and not be recognized as clinics. This commenter explained that, regardless of the setting, outpatient services should be paid the same reimbursement rate.

Response: This regulation does not alter the requirements for participation in the Medicaid program as an outpatient hospital facility. For purposes of the Medicaid program, the regulation continues to require that a facility be licensed or formally approved as a hospital by an officially designated authority for State standard-setting and meet the requirements for participation in Medicare as a hospital. Moreover, this regulation does not preclude a State from establishing identical payment rates for outpatient rehabilitation services whether furnished in an outpatient hospital setting or in a non-hospital clinic setting. Indeed, this regulation would encourage this practice because rehabilitation services that are covered under a non-hospital benefit category would be considered to be in that benefit category rather than an outpatient hospital service.

Comment: One commenter stated that 8000 or more students will be negatively impacted by the proposed rule changes. The commenter suggested that the reimbursement dollars for outpatient hospital services should be used to fund services in schools.

Response: We respectfully disagree. Under Title XIX of the Social Security

Act, specific services are listed as coverable under the Medicaid program. The outpatient hospital benefit category recognizes the unique nature of services furnished by an outpatient hospital facility. Services furnished in schools or other non-hospital settings, or by non-hospital practitioners, can still be covered under other benefit categories.

Therefore, this regulation does not prohibit States from covering services provided in schools under Medicaid benefit categories. Rather, the regulation would define services that may be covered under the outpatient hospital services benefit under a Medicaid State plan to focus on those services unique to an outpatient hospital.

Further, federal Medicaid funds are not specifically allocated to outpatient hospital services, and thus a shift in coverage from one benefit category to another would not necessarily affect available funding for any particular service. In other words, this rule would not divert federal funding from schools. Federal funding is available to match State or local non-federal expenditures for covered Medicaid services in accordance with a State's federal medical assistance percentage and the reimbursement methodology described in the State's approved Medicaid plan.

Comment: A commenter requested clarification of the impact on the provision of rehabilitation services in outpatient settings. The commenter noted that this impact could affect services in State psychiatric hospitals for patients over 64 and undermine progress on the President's New Freedom Initiative.

Response: The regulation clarifies the scope of outpatient hospital facility services that are eligible for federal financial participation. To the extent that rehabilitative services are recognized under the Medicare outpatient prospective payment system or an alternate fee schedule for outpatient hospital services and are not defined in a State's Medicaid plan under another Medicaid benefit, the services may remain under the outpatient hospital benefit category. We note that the psychiatric hospitals in question are typically inpatient facilities, usually with little or no outpatient volume. These institutions provide care to Medicaid inpatients under a separate Medicaid benefit category for inpatient hospital services that would not be affected by this rule.

Comment: One commenter suggested that the regulation could result in non-coverage of certain pathology services. This commenter recommended that a special provision be included in the regulation to allow pathology services

provided by outpatient hospitals to be reimbursed under the outpatient hospital benefit category using the appropriate State plan fee schedule.

Response: The intention of the regulation is to appropriately recognize the unique nature of outpatient hospital services. Pathology services are typically delivered by physicians and in some instances are an integral part of a hospital service. To the extent that the pathology services in question are recognized under the Medicare outpatient prospective payment system or an alternate Medicare fee schedule for outpatient hospital services and are not defined in a State's Medicaid plan under another Medicaid benefit, the services may be included by the State under the outpatient hospital benefit category. To the extent that the services would be covered by the State plan under the physician services benefit, they should not be included in the Medicaid outpatient hospital services benefit.

Comment: A commenter requested that CMS include a provision in the final rule that would allow reimbursement of clinical diagnostic lab services as an outpatient hospital services as long as there is not duplicative payment for the services. The commenter noted that CMS should make clear that outpatient hospitals and free-standing clinics may continue to receive payment for these services.

Response: We did not accept this comment because we believe it is more consistent with statutory requirements for clinical diagnostic laboratory services to be claimed under the Medicaid benefit category for laboratory services. Laboratory services are a mandatory benefit category, and thus the services would remain covered even though not included as outpatient hospital services. Only when reported separately can CMS and States ensure consistency with the unique requirements applicable to laboratory services. Laboratories are subject to a different regulatory review than outpatient hospitals, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, implemented in part by regulations at 42 CFR part 493. Moreover, section 1903(i) of the Act limits Medicaid reimbursement for clinical diagnostic laboratory services to the amount of the Medicare fee schedule for the services on a per test basis. Implementation of these provisions will be improved by ensuring that laboratory services are claimed under the benefit category specifically for such services.

Comment: One commenter stated that excluding rehabilitative, school-based

and practitioner services from the definition of outpatient hospital services cuts funding and the availability of services.

Response: As previously explained, federal Medicaid funds are not specifically allocated to outpatient hospital services. The Centers for Medicare and Medicaid Services matches expenditures for covered Medicaid services in accordance with a State's federal medical assistance percentage and the reimbursement methodology described in the State's Medicaid plan. The purpose of the regulation is to define the scope of outpatient hospital services unique to the outpatient hospital setting and for which a hospital may receive a facility payment, and not to limit the availability of services under other benefit categories. The above services are provided by Medicaid qualified professionals and are reimbursed on a fee-for-service basis regardless of the setting in which the services are performed.

Comment: One commenter stated that CMS's decision to eliminate reimbursement for Medicaid services covered in the State Plan is not consistent with the Medicaid statute.

Response: The regulation does not eliminate any Medicaid benefit category recognized under the Social Security Act or the settings in which those services may be rendered. By clarifying the scope of outpatient hospital facility services available for Federal financial participation, CMS intends to recognize the nature of services that are uniquely furnished by outpatient hospitals, including the high overhead facility costs associated with such services. At the same time, we do not believe it is effective and efficient to include other services that do not have those unique characteristics in the outpatient hospital services benefit category. These other services are more appropriately included in other benefit categories, and paid at rates warranted by the nature of the service regardless of the setting. Thus, we believe that this rule is consistent with the Medicaid statute and CMS's charge to preserve the fiscal integrity of the program.

Comment: One commenter stated that the definition of Medicare criteria for "provider-based status" is a complicated standard. The commenter suggested that some hospitals that have the authority to claim a facility fee under the preceding Medicaid rules would only receive payments for professional services under the proposed rule.

Response: The intention of the regulation is to recognize the high

facility overhead expenses that are associated with the delivery of services unique to an outpatient hospital or a department of an outpatient hospital that, according to 42 CFR 413.65, "is either created by, or acquired by, a main provider for the purpose of furnishing health care services of the same type as those furnished by the main provider under the name, ownership, and financial and administrative control of the main provider." The commenter is correct in that only a provider-based entity that is providing outpatient hospital services as defined under the regulation may receive Medicaid payment under the outpatient hospital benefit category.

This final regulation would not permit Medicaid payment under the outpatient hospital service benefit for services furnished in settings that are not within the scope of the certified hospital, even if the setting is owned by the hospital and provider-based. In other words, the services must be furnished by the main hospital or the department of the hospital (a provider-based entity furnishing the same type of care as the hospital). However, States may cover and pay for such a service under other appropriate State plan benefit categories.

Comment: One commenter stated that excluding physician, physical, occupational and speech therapy, clinical diagnostic laboratory services, ambulance services, durable medical equipment and outpatient audiology services from the definition of outpatient hospital services does not represent the reality of the scope of care provided in hospital settings. The commenter notes that CMS did not demonstrate that access to these services is available in the community and outside of a hospital outpatient department.

Response: We are not discouraging hospitals from providing primary and preventive care services in hospital settings. The proposed rule makes a distinction between outpatient services that are billed by a recognized hospital facility in which services are furnished and those billed by physicians and other professionals. Under Medicaid, States generally pay a fee schedule rate for physician and other professional services and a separate rate to hospitals providing outpatient services. Physicians and other professionals cited in the example, who provide services in a hospital facility, will be reimbursed at the professional rate.

Comment: One commenter noted that overlap in Medicaid service categories is a long-standing Medicaid policy and cited a CMS response to comments on

a nurse-midwife regulation: "While we view each category of service as separate and distinct, the categories are not mutually exclusive. Some services * * * can be classified in more than one category. It is also possible that a service provided may meet the requirements under one category and not another even though, as a general rule, the service could be classified under either category. The specific circumstances under which a service is provided and how the provider bills for the service determines how the service is categorized and which regulatory requirements apply."

Response: Through this regulation, we are seeking to clearly distinguish between services unique to an outpatient hospital facility and services of practitioners to permit targeting of coverage and payment. The regulation would assist in avoiding duplicative or excessive payments that could result from the overlap of the outpatient hospital service definition and a professional service definition.

Comment: A commenter stated that by "limiting the locations where services may be provided and requiring separation of professional and other charges, the proposed regulation will result in the reduction of the quality of care provided to consumers," particularly any aspects of care for behavioral health clients who require services in settings outside the walls of the clinic and require professional and non-professional efforts which address aspects of behavioral health problems that are not directly treatment of the client. Further, the commenter noted that providing the services outside of the clinic historically allowed for a high quality of care.

Response: As previously stated, the intention of the regulation is not to limit or prescribe the location where a Medicaid service may be rendered. Any qualified Medicaid provider may render a Medicaid covered service in a non-institutional setting, including a hospital. The regulation does not impact the definition of a clinic service (42 CFR 440.90). A behavioral health client who is Medicaid eligible may receive a service, from a qualified Medicaid provider, defined under the State plan within a clinic or in the community. We do not understand the comment that professional and non-professional efforts may be required to provide Medicaid services to an individual because only a Medicaid qualified provider may render and receive payment for a non-institutional professional service.

Comment: A commenter noted that the proposed rule change does not

define the terms "traditional," "non-traditional," "facility services," or "non-facility services."

Response: In issuing this regulation, we have looked to the plain language of the statutory Medicaid benefit categories to distinguish between services uniquely furnished by an outpatient hospital facility and those furnished by individual practitioners or other providers. We note that both outpatient hospitals and clinics are eligible for facility payments, but they are included in the statute as separate benefit categories. When we used the terms "traditional" and "non-traditional" in the preamble, we meant to distinguish between those services generally recognized as outpatient hospital services.

As discussed in the proposed rule, we did not consider services to be appropriately included in the outpatient hospital services category solely for purposes of including those services in the outpatient hospital upper payment limit.

Comment: One commenter referenced CMS's comments in the 1983 revised definition of outpatient hospital services "States would still be required to cover the other mandatory services (such as physician services) and some optional services when they are provided in the outpatient hospital setting * * *." The commenter argued that CMS is not concerned with an overlap in service definitions. Instead, the commenter contended, CMS's concern is with reimbursing hospitals higher rates for Medicaid services, such as physician services. The commenter maintained that the regulation represents new policy and not a simple clarification of the outpatient hospital service definition.

Further, the commenter stated that CMS's contention that the overlap in service definitions may not have been the intent of the Congress and that the Medicaid statute was enacted over forty years ago, yet CMS never took issue with varied payment rates in service setting or required consistent service definitions between Medicare and Medicaid.

Response: As previously discussed we are not restricting the settings in which Medicaid covered services may be provided to covered individuals by qualified Medicaid providers. The purpose of the regulation is to define the scope of outpatient hospital services unique to the outpatient hospital setting and for which a hospital may receive a facility payment, and not to limit the availability of outpatient services under other benefit categories. The rule does not prohibit the provision of any

covered Medicaid physician service in an outpatient setting.

The commenter is correct that CMS has not previously restricted State flexibility to include services under the outpatient hospital benefit, even when the sole purpose was to affect the outpatient hospital upper payment limit. This rule represents a new initiative to preserve the fiscal integrity of the Medicaid program.

We do not intend through this regulation to deny coverage of any Medicaid covered service to an individual eligible for Medicaid or deny payment to a qualified Medicaid provider. The provisions of this regulation help to ensure that coverage and payment under State plans will be consistent with economy, efficiency and quality of care.

Comment: A commenter cited services that are excluded from Medicare coverage that may be covered by a state under its Medicaid program: Dental services, vision care, foot care and immunizations. The commenter noted that these services 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.

Response: As previously discussed, the services included in the comment are covered under a distinct Medicaid benefit category and would have specific provider qualifications, coverage provisions and payment policies. The services may continue to be provided to a Medicaid beneficiary in any non-institutional setting, including outpatient hospitals, by a qualified Medicaid provider. In addition, CMS allows States discretion in setting payment rates that meet the requirements of section 1902(a)(30)(A) of the Act and regulations at 42 CFR 430.10 and 447.204.

Comment: One commenter stated that Medicare does not recognize dental services under OPPS or an alternative payment methodology, whereas the service is a covered benefit under the Medicaid program. To be consistent with the Medicare program, the commenter suggested that CMS remove the statement that outpatient hospital services may be furnished "by or under the direction of a dentist" from the regulatory language.

Response: Medicare does recognize a number of dental procedures provided in hospital settings. In addition, the regulation does not prohibit the provision of a covered Medicaid dental procedure in an outpatient hospital. However, the regulation will require

that the payments for dental services be reimbursed under the Medicaid dental benefit category, which is distinct from the outpatient hospital benefit category. Again, States have discretion in setting payment rates for dental services within the authority of section 1902(a)(30)(A) of the Act and regulations at 42 CFR 430.10 and 447.204.

Comment: A commenter explained that the regulation may be at odds with State flexibility in establishing payment methodologies and rates, noting that one of CMS' rationales is to prevent States from paying higher rates in hospitals for the same services paid at lesser rates in other facilities. The commenter noted that CMS did not provide a basis that the services provided in the hospital setting are the same as services provided in other settings or a basis for paying the same amount regardless of the setting. The commenter stated that it is appropriate to pay hospitals higher amounts for services provided in hospital settings because of the higher costs associated with the hospital. Further, the commenter suggested that CMS is attempting to re-define the coverage rules for outpatient hospital services in order to place limitations on the payment for those services.

Response: We distinguish in this regulation between coverage of services that are uniquely furnished by an outpatient hospital and coverage of services furnished by practitioners or other providers. We do not understand the comment that services rendered by professionals, or qualified Medicaid practitioners, would be different in outpatient hospital settings than those provided by the same professional in a private practice or other community setting. But, if so, a State has flexibility to vary the payment rate for practitioner or other provider services furnished in an outpatient hospital setting.

As previously discussed, one impetus for this regulation was that the ambiguous coverage definition in the Medicaid regulations for outpatient hospital services allowed States to artificially increase the outpatient hospital upper payment limit and direct supplemental payments to a select group of hospitals. Therefore, to prevent this artificial inflation of the upper payment limit we must clarify the covered facility services that may be defined as part of the outpatient hospital benefit category and, thus, may be included in the applicable UPL calculation.

Comment: Several commenters noted that some hospitals treat the hospital facility payment as an all-inclusive rate and pay physicians furnishing services to hospital outpatients. These

commenters stated that the Medicare program recognizes this unique reimbursement methodology and waives requirements under OPPS for certain facilities.

Response: We considered whether it would be warranted to permit an exception for those facilities with a waiver of Medicare OPPS requirements. Since the purpose of this regulation is to align the definition of Medicaid outpatient hospital facility services with Medicare's definition, we interpret the phrases "would be included, in the setting delivered" and "paid by Medicare as an outpatient hospital services under an alternate payment methodology" at 42 CFR 440.20(a)(4) of this rule to recognize those hospitals that receive the exception to the OPPS requirements under the Medicaid definition. Therefore, States may define the outpatient benefit to include an exception for these hospitals, limited to the all-inclusive services that are recognized by Medicare. However, the State must furnish to CMS documentation that a hospital provider has received the Medicare exception and include a reasonable estimate of Medicare payment for the providers in the upper payment limit demonstration by using alternate data sources recognized by Medicare specifically for those providers.

Comment: Several commenters were concerned that moving reimbursable services out of outpatient hospital settings would reduce access to services. One commenter noted that Medicaid practitioner fees are inadequate and do not promote access of primary care outside of hospital-based physician practices. The commenter noted that most primary care physician practices within her state have converted to provider-based entities in order to receive higher payment rates.

Response: States have considerable flexibility under federal law to establish payment rates for Medicaid services that are sufficient to ensure access to services while meeting the requirements of section 1902(a)(30)(A) of the Act and regulations at 42 CFR 430.10 and 447.204. CMS does not have the authority to require States to increase payment rates for Medicaid services. The outpatient hospital benefit provides for coverage of those services unique to outpatient hospitals and payments can take into account the overhead costs in hospital settings. To the extent that providers are "converting" to provider-based entities with the sole intention of receiving increased reimbursement, we do not view this as an appropriate means of receiving higher

reimbursement under the Medicaid program.

Comment: Several commenters stated that CMS' concerns with duplicative payments were baseless because State claims processing systems screen for duplicative payments.

Response: The potential for duplicative payments is merely one reason for implementing this regulation. In addition, we are attempting to align the Medicaid definition of outpatient hospital services with the applicable UPL, provide transparency to the services covered under the benefit, and clarify the appropriate services under the benefit that may be claimed for federal financial participation.

Comment: One commenter stated that CMS did not present an adequate justification for the regulation and that State Plan Amendment reviews allow CMS to address the requirements authorized under the proposed rule.

Response: As discussed in the proposed regulation, the ambiguous definition of outpatient hospital services does not clearly prevent including in the benefit non-hospital facility services that would not be included in the benefit under the Medicare program. Therefore, we disagree that the provisions of the regulation may be carried out through State plan review.

Comment: One commenter stated that the intent of the Congress was to separate the Medicaid and Medicare program and not "equate" Medicaid services to Medicare.

Response: One purpose of this amendment is to align the Medicaid definition more closely to the Medicare definition in order to improve the functionality of the applicable upper payment limits under 42 CFR 447.321 (which are based on a comparison to Medicare payments for the same services), provide more transparency in determining available coverage in any State, and generally clarify the scope of services. While we understand the difference between the populations served under the Medicare and Medicaid programs, we believe that the services recognized under the Medicare OPPS and the alternate fee schedules for outpatient hospital services encompass outpatient hospital facility services that are typically provided to the general public.

Comment: Several commenters stated that the regulation is inconsistent and confusing because allowable services under the Medicaid State plan overlap with some of the services paid for under the Medicare OPPS. For instance, one commenter noted that OPPS pays for prosthetic devices, prosthetics, supplies, and orthotic devices, durable medical

equipment, and clinical diagnostic laboratory services and prosthetic devices and durable medical equipment are "separate" Medicaid State plan service categories.

In addition, the commenter remarked that OPPTS coverage definition for prosthetics and DME are more restrictive than what is allowable under the Medicaid State plan. Several commenters requested that CMS specify whether as service covered under the Medicaid regulations as a separate State plan category of services is considered an outpatient hospital service when furnished in an outpatient hospital facility and included in OPPTS. One commenter requested that CMS justify treating a service recognized under Medicare as a hospital service differently under the Medicaid program.

Response: As we indicated in the proposed rule, services provided under a distinct Medicaid benefit category will operate under the coverage and reimbursement provisions for those services under the Medicaid State plan. If a service is described under a separate benefit category in the State plan that service may still be provided in an outpatient hospital setting. Coverage and payment for that service will be governed by the relevant provisions in the State plan for the service, and any applicable federal restrictions. For example, clinical diagnostic laboratory services are subject to a statutory limit regardless of setting, described at section 1903(i) of the Act, up to the amount that Medicare pays on a per test basis. Further, outpatient DME under Medicaid is paid under the home health benefit, as medical equipment. There is a separate benefit category that includes prosthetic devices.

Comment: One commenter stated that 42 CFR 419.2(b) does not contain an all-inclusive list of costs allowable within OPPTS.

Response: In this rule, we allow coverage of all of the outpatient hospital services recognized under the Medicare OPPTS or an alternate fee schedule paid for outpatient services provided in hospitals that are not included in another benefit category under the State plan. The referenced regulations are the authority under the Medicare program for OPPTS and the alternate fee schedule for outpatient services. Services or costs that are allowable under that authority, whether specifically listed or not, would be allowable if not otherwise covered.

Comment: One commenter questioned the impact of the regulation on EPSDT services or services that are difficult for Medicaid recipients to access (such as dental services). Specifically, the commenter requested that CMS clarify if

any upper payment limits apply to these services and suggested that the payment rates in hospitals should not be limited to community rates because the community rates do not recognize outpatient overhead expenses. The commenter explained that limiting the outpatient hospital scope of services "to reduce payments to hospitals" undermines the Congressional intent and creates access issues.

Response: CMS is not discouraging hospitals from providing certain services in the hospital setting; this regulation addresses only the benefit category under which such services should be claimed. EPSDT and dental services are distinct Medicaid benefit categories and the coverage and payment provisions for those services are described separately from outpatient hospital services in the Medicaid State plan.

As previously discussed, States have discretion in defining the payment methodology for non-institutional services within the authority of section 1902(a)(30)(A) of the Act and regulations at 42 CFR 430.10 and 447.204. As of the publication of this regulation, there are no upper payment limits for services provided to Medicaid outpatients other than in clinics and outpatient hospital settings. Again, the purpose of the regulation is not to reduce payments, but to clarify those services that are uniquely provided in outpatient hospital settings.

Comment: A commenter requested that CMS explain the rationale behind eliminating a State's ability to pay hospitals' bundled rates. The commenter argued that since OPPTS is a bundled methodology designed to promote efficiency and discourage over-utilization, States should have the ability to continue to bundle hospital services in an effort to promote efficiencies beyond those provided for under OPPTS.

Response: The regulation does not define how States may structure base Medicaid payments for outpatient hospital services, but removes from that bundle services that are not unique to the outpatient hospital. States continue to have the ability to "bundle" all covered outpatient hospital services and make payments within the applicable upper payment limit for those services. To the extent that the commenter is referring to "bundling" facility and professional services, we do not view such bundles as efficient or economical and note that the majority of private payers make distinct payments for facility and professional costs.

Comment: One commenter requested clarification as to the impact on clinic

services based on the inclusion of clinics under title of the proposed regulation.

Response: In response to this comment, we determined that it was confusing to add the word "clinic" without the entire phrase "outpatient hospital clinic." The intent was to clarify that outpatient hospital services include outpatient services provided either in a hospital facility itself or in a clinic that meets the standards for provider-based status as a department of the hospital. We have thus revised the title of the final regulation to clarify that the service clarifications in the final rule apply only to outpatient hospital services.

Comment: One commenter noted that the proposed definition of outpatient hospital services will remove services from State DSH calculations and further cut hospital Medicaid reimbursement.

Response: One of the purposes of the regulation is to clarify the services that are available for federal financial participation under the outpatient hospital benefit category. We believe the services included in the proposed rule described those services that are unique to outpatient hospital settings. To the extent that States are currently defining additional services as outpatient hospital services in order to include their costs in calculating the hospital-specific limit under the disproportionate share hospital (DSH) program, those services would no longer be allowable in the DSH calculation under the final rule. On the other hand, payment for those services would not be subject to outpatient hospital upper payment limits.

Comment: One commenter urged CMS to specify that outpatient hospital services must be provided in provider-based settings.

Response: As § 440.20(4)(ii) explains, outpatient hospital clinic and hospital facility services "are furnished by an outpatient hospital facility, including an entity that meets the standards for provider-based status as a department of an outpatient hospital as set forth in § 413.65 of this chapter." As mentioned previously, the outpatient hospital services benefit includes only services of hospitals and departments of hospitals, not services provided in other settings, even if hospital-owned and provider-based. All other Medicaid covered services provided in a hospital-owned setting must be covered and paid for under a distinct Medicaid State plan benefit category and reimbursement methodology.

Comment: One commenter requested additional clarification on the scope of services paid under alternate Medicare

payment methodologies as outpatient hospital services that would be included under this proposed definition.

Response: The final rule allows for coverage of any service that may be claimed as an outpatient hospital institutional service under the Medicare program with the exception of those services that are covered under another Medicaid benefit category in the State plan. Please refer to Medicare rules and guidance for further information on the scope of the Medicare outpatient hospital benefit.

Comment: One commenter requested that CMS “confirm that costs for services not explicitly excluded from the OPPTS are therefore includable (assuming that these services meet the other proposed criteria).”

Response: Only those services that are included in OPPTS or an alternate Medicare fee schedule may be included as part of the Medicaid outpatient hospital benefit category.

Comment: One commenter stated that Title 42, § 410.20(b) of the CFR also excludes certain categories of hospitals from the Medicare OPPTS. The commenter requested that CMS clarify that services included under this provision may be defined as Medicaid outpatient hospital services.

Response: The commenter was apparently referring to 42 CFR 419.20, since 42 CFR 410.20 refers to coverage of physician services. This rule does not require that States apply the OPPTS payment system, but only that the definition of outpatient hospital services be consistent with the scope of services included under OPPTS. In other words, whether a hospital is excluded from OPPTS or not, the scope of outpatient hospital services would be uniform for both Medicare and Medicaid.

Comment: Many commenters stated that the rule would eliminate rural health clinics (RHCs) as eligible providers for DSH payments, even though their RHCs are largely an extension of a hospital, wherein the hospital: “employs the RHC’s personnel, pays its bills, performs quality assurance, credentials the physicians and physician assistants employed by the RHC, and provides medical supplies to the RHC.” These commenters stated that eliminating RHCs from State DSH calculations would “impede care” in rural areas and create “financial incentives to use scarce and expensive emergency department services” rather than less costly RHC facilities. Many of these commenters referred to a Fifth Circuit Court of Appeals decision which allowed for the inclusion of services rendered in RHCs to be part of the outpatient hospital DSH calculation.

Several commenters opined that CMS does not have the authority to overturn the decision.

Response: The Fifth Circuit Court of Appeals decision was based in large part on an interpretation that, under then-current regulations, services rendered in hospital-based RHCs meet the definition of outpatient hospital services (and may be included in a hospital’s DSH calculation even though paid as RHC services). The decision relied on the ambiguity in those regulations permitting an overlap between services that meet the definition of outpatient hospital services and also meet the definition of a service under another benefit category. Under this final rule, there would be no such overlap, and the services at issue in the Fifth Circuit case would have to be treated consistently for all purposes. This means: that unless the services provided in the RHCs meet the new definition of Medicaid outpatient hospital services, because the RHCs are provider-based outpatient departments of a hospital in accordance with 42 CFR 413.65, and the Medicaid agency recognizes the RHCs consistently as Medicaid outpatient hospital service providers, the services provided in rural health clinics could no longer be recognized as outpatient hospital services.

This makes sense because the payment systems for hospitals and for RHCs are completely different. Hospital payments are not required to reflect actual costs, but must include an adjustment to take into account the situation of hospitals that serve a disproportionate share of low income patients. In contrast, RHCs are paid through a prospective payment system based on actual costs that should reflect essentially the full cost of Medicaid services. There is no need for adjustments to reflect higher costs for RHCs, because the payment level is on a full cost basis.

Comment: Many commenters opposed the proposed rule because the upper payment limit references to the Medicare cost report (CMS 2552) do not recognize graduate medical education (GME) costs. Several of these commenters remarked that restricting GME payments violates the 1-year congressional moratorium, passed as part of the U.S. Troop Readiness, Veterans Care, Katrina Recovery, and Iraq Appropriations Act of 2007, stating that the regulation presents “restrictions on Medicaid graduate medical education (GME) payments.” One commenter noted that GME costs “are included on hospital cost reports and Medicare pays them,” while another

commenter stated that GME costs are located on the Medicare cost report at Worksheet B, Part 1, Column 25. Several commenters stated that the exclusion of GME from the cost report references used to calculate outpatient upper payment limits will have a tremendous financial impact on teaching hospitals.

Response: This regulation does not prohibit States from covering or paying for GME and thus does not address the issues set forth in the proposed rule that was subject to a congressional moratorium. In addition, the provisions of the proposed regulation at 42 CFR 447.321(b)(1)(i)(B) have not been included in this final regulation.

However, regardless of whether a Medicaid program determines to make a GME payments or adjustments for outpatient hospital services, the Medicare program does not make GME payments for outpatient hospital services. As we explained in the proposed rule, the aggregate UPL based on Medicare is reasonable only when there is a consistent definition of outpatient hospital services between Medicare and Medicaid.

Comment: One commenter requested additional information regarding the overlap between the proposed changes to 42 CFR 440.20(d) and diagnostic services under the proposed rehabilitative services regulation under 42 CFR 440.130(d) particularly, how States should reconcile the provisions.

Response: We have reviewed the changes proposed to 42 CFR 440.130(d) and do not see a conflict with the regulatory changes implemented in this final regulation. Rehabilitative services fall under a distinct Medicaid benefit category and are defined and paid under the Medicaid State plan provisions for rehabilitative services.

III. Provisions of the Final Regulations

As a result of our review of the comments we received during the public comment period, we are making revisions to the proposed regulation published on September 28, 2007. The title of the proposed regulation is revised to make it clear that the definition of outpatient hospital services also applies to services provided in outpatient hospital clinics. The title will now read: “Outpatient hospital facility (including outpatient hospital clinic) services.” In addition, we have modified the phrase “a department of an outpatient hospital” at § 440.20(a)(4)(ii) to read “a department of a provider” as this exact terminology is used in the referenced Medicaid provider-based definition at 42 CFR 413.65. We are also reserving action on the proposed changes to 42 CFR 447.321, the

outpatient hospital and clinic upper payment limits. We may address these provisions at a future date. All other provisions are adopted as proposed.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended, the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-04), and Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for rules with economically significant effects (\$100 million or more in any 1 year). This is not a significant or economically significant rule because the size of the anticipated reduction in Federal financial participation is not estimated to have an economically significant effect of more than \$100 million in each of the Federal fiscal years 2008 through 2012.

The RFA requires agencies to analyze options for regulatory relief of small businesses if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that small entities include small businesses, non-profit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by being non-profit organizations or by meeting the SBA definition of a small business of having revenues of less than \$7.0 million to \$34.5 million in any 1 year. The Secretary has determined that this final rule would not have a direct impact on

providers of outpatient hospital services that furnish services pursuant to section 1905(a)(2)(A) of the Act. This rule will directly affect States and we do not know nor can we predict the manner in which States will adjust or respond to the provisions of this rule.

CMS is unable to determine the percentage of providers of outpatient hospital services that are considered small businesses according to the Small Business Administration's size standards with total revenues of \$7.0 million to \$34.5 million or less in any 1 year. Individuals and States are not included in the definition of a small entity. In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we defined a small rural hospital as a hospital that is located outside of a Core Based Statistical Area for Medicaid payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined and the Secretary has determined that this final rule will not have a direct significant economic impact on small rural hospitals. The rule would directly affect States and we do not know nor can we predict the manner in which States would adjust or respond to the provisions of this rule.

Section 202 of the Unfunded Mandates Reform Act (UMRA) of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold level is approximately \$130 million. Since this rule will not mandate spending in any 1 year of \$130 million or more, the requirements of the UMRA are not applicable.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs of State and local governments, preempts State law, or otherwise has Federalism implications. Since this rule would not impose any costs on State or local governments, preempt State law, or otherwise have Federalism implications, the requirements of E.O. 13132 are not applicable.

B. Anticipated Effects

On March 3, 2008, the Committee on Oversight and Government Reform published a report titled: "The Administration's Medicaid Regulations: Summaries of State Responses.¹⁷" The report provided a state-by-state analysis of the anticipated monetary effects of several proposed Medicaid regulations, including CMS 2213-P. In addition, the report quoted specific concerns from Medicaid Directors in relation to the proposed rules.

Of the States that participated in the analysis, twenty-two reported no potential loss in FFP, four reported a specific monetary loss, and eighteen reported there may be a potential loss of FFP but were unable to estimate a monetary amount as a result of CMS 2213-P. One year after implementation of CMS 2213-P, California estimated a potential \$266 million loss; while Illinois projected a loss of \$700 million after one year. In addition, Missouri estimated losses of approximately \$6 million and Louisiana calculated a \$3 million impact after one year.

Based upon our review of the Medicaid Directors' concerns and the public comments received in response to the proposed rule, we believe that the potential for monetary loss is overstated in the analysis due to misunderstandings of the goal and scope of the proposed rule. Though many of these misunderstandings are clarified in our responses to the public's comments, we will attempt to address the primary concerns detailed in the Committee's report.

The purpose of this final regulation is to improve the functionality of the applicable upper payment limits under 42 CFR 447.321 (which are based on a comparison to Medicare payments for the same services), provide more transparency in determining available hospital coverage in any State, and generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category.

As discussed in detail in the response to public comment, the rule will not eliminate any covered Medicaid services under Title XIX, restrict the provision of a Medicaid service by a qualified Medicaid provider to a Medicaid outpatient, or dictate the methodologies through which States may reimburse providers for services in accordance with applicable federal statute and regulations. In our review of State plan amendments for outpatient hospital services, CMS noted only one State that would be in violation of the

proposed rule at the time of publication. Since the publication of the proposed rule, the State has taken measures to remove from the State plan those services that would no longer be covered as part of the outpatient hospital benefit.

In response to this concern, we emphasize that States continue to have the authority to pay for any Medicaid service that is rendered in a non-institutional setting by a qualified Medicaid provider and establish economic and efficient payment rates for those services that attract sufficient willing and qualified providers. Removing these services from the outpatient hospital benefit category does not equate to non-coverage or non-payment of the services in outpatient hospitals or other non-institutional settings. Therefore, we do not believe there will be a monetary impact as States will continue to have the ability to receive Federal matching funds for covered Medicaid services paid under the appropriate benefit category. However, to the extent a State would not choose to adjust payment methods appropriately, there could be a financial impact on the State. But, this is at the discretion of the State and CMS can not quantify this possibility.

Instead, the regulation calls for States to define Medicaid services under the appropriate coverage and payment provisions of the State plan. Currently, services provided in non-institutional settings, with the exception of outpatient hospitals and clinics, do not have specific upper payment limits defined in regulation. States are free to set economic and efficient State plan payment rates in consideration of the Medicaid costs of providing services within the various settings where outpatients receive care. In some instances, this could result in increased Medicaid payments for some of these services. Therefore, we do not anticipate that the regulation defining what is covered as an outpatient hospital facility service will result in significant reductions in FFP for Medicaid service providers or place significant administrative burdens upon States.

We specifically requested comments on the regulatory impact analysis and the comments and responses are summarized below. Several providers and States noted a loss of specified or unspecified dollar amounts that would result from the change in the coverage definition. However, the public comments did not provide for any concrete evidence that would support such a significant reduction in FFP. Therefore, we are unable to determine if those reported monetary losses are

based upon misunderstandings of the regulation's scope and intent or whether States' action in response to the regulation, within allowable Medicaid authority, will offset the potential losses.

The second major concern voiced through the public's comments and the Committee's report addressed the potential FFP and administrative impact of the upper payment limit requirements. Particularly, the Illinois Medicaid Director responded to the Committee's report by stating that CMS 2213-P "will constrain the ability of states like Illinois to use the room in the UPL to supplement their relatively low federal DSH allotments." Several public commenters and Medicaid Directors also indicated that the UPL requirements would place new administrative burdens upon State Medicaid agencies. We are puzzled by the comments because the proposed rule did not deviate from the current regulatory definition of the Medicaid outpatient hospital upper payment limit, a reasonable estimate of Medicare payment for equivalent services, or CMS's historic expectations of a reasonable upper payment limit for the services. However, these types of concerns should be alleviated because the clarifying provisions to the UPL regulation have been removed from this final rule.

Finally, based on the public comments, many felt that we failed to fully discuss the potential impact of the regulation on State disproportionate share hospital calculations for outpatient hospital services. We believe that Louisiana's Medicaid Director raised this issue in the Committee report by stating: "Implementation of the proposed rule may cause a loss of essential medical services in underserved rural areas." As noted in the response to public comments, a rural health clinic or other Medicaid provider that does not meet the definition of a department of a hospital or outpatient hospital and/or is paid under a State plan reimbursement methodology other than that defined for outpatient hospital services may not be considered in a State's Medicaid DSH calculation for outpatient hospital services.

Louisiana is currently including rural health clinics in the Medicaid DSH calculation. Because the scope of services provided within these clinics and what, if any, relationship exists between the clinics and a main hospital provider are not transparent in the State plan, CMS is unable to determine if the clinics are departments of an outpatient hospital and could continue to be

included in the State's DSH calculation. Therefore, we do not dispute the amount reported to the Committee by Louisiana. Likewise, for any other State that is including the uncompensated costs of services that would no longer be considered outpatient hospital services there would be a potential reduction in uncompensated costs that could be recognized through Medicaid DSH payments. However, we believe that most States could find other allowable uncompensated inpatient and outpatient hospital costs that could be recognized for Medicaid DSH purposes and that, at least in part, offset potential losses that result from this regulation.

Public Comments

Within the proposed regulation's regulatory impact analysis, we noted that data was unavailable to calculate the exact impact of the regulation because of the lack of transparency with State outpatient hospital coverage provisions and the resulting payments for services. However, we stated that we did not believe that the regulation would have a significant impact because we believed that a majority of States were in compliance with the provisions of the proposed rule. We specifically requested public comments concerning the regulatory impact analysis and have revised the analysis as part of this final rule.

Comment: Several commenters opposed the rule because of CMS's inability to conduct a regulatory impact analysis. One commenter argued that "before a regulation of this magnitude is implemented, the impact should be specified and addressed." Some commenters also stated that, absent an impact analysis, the rule was bad public policy and should be withdrawn. Several commenters argued that the impact analysis was in violation of Executive Order 12886 and the Congressional Review Act.

Response: CMS specifically requested that the public provide comments on the regulatory impact analysis and data to help develop the analysis. We have revised the statement accordingly.

Comment: A number of commenters stated that since CMS has identified only one State that would violate the proposed rule, the administrative burden and restrictions in defining the Medicaid outpatient hospital benefit placed upon States is unjustified.

Response: We believe that the vast majority of States are in compliance with the regulation. Therefore, we do not agree that the regulation would cause a significant administrative burden. As detailed in the proposed regulation, we are implementing the

regulation to ensure consistency between the Medicaid outpatient hospital service definition and the applicable UPL requirements, provide more transparency in determining available hospital coverage in any State, and generally clarify the scope of services for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category. As stated previously, we are not including any changes to the UPL provisions in this final rule, which should alleviate concern over administrative burden at this time. If we address these provisions in the future, we will respond to comments on the associated administrative burden at that time.

Comment: One commenter noted that the RIA should include the potential impact on units of government and disproportionate share hospital payments.

Response: Again, we believe that the majority of States are in compliance with the clarification of the definition of Medicaid outpatient hospital services. The revised RIA includes a discussion of DSH payments.

List of Subjects in 42 CFR Part 440

Grant programs—health, Medicaid.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 440—SERVICES GENERAL PROVISIONS

■ 1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. Section 440.20 is amended by revising the section heading and paragraph (a) to read as follows:

§ 440.20 Outpatient hospital facility (including outpatient hospital clinic) services and rural health clinic services.

(a) Outpatient hospital services means preventive, diagnostic, therapeutic, rehabilitative, or palliative services that—

- (1) Are furnished to outpatients;
- (2) Are furnished by or under the direction of a physician or dentist;
- (3) Are furnished in a facility that—
 - (i) Is licensed or formally approved as a hospital by an officially designated authority for State standard-setting; and
 - (ii) Meets the requirements for participation in Medicare as a hospital;
- (4) Are limited to the scope of facility services that—
 - (i) Would be included, in the setting delivered, in the Medicare outpatient

prospective payment system (OPPS) as defined under § 419.2(b) of this chapter or are paid by Medicare as an outpatient hospital service under an alternate payment methodology;

(ii) Are furnished by an outpatient hospital facility, including an entity that meets the standards for provider-based status as a department of a provider set forth in § 413.65 of this chapter;

(iii) Are not covered under the scope of another Medical Assistance service category under the State Plan; and

(5) May be limited by a Medicaid agency in the following manner: A Medicaid agency may exclude from the definition of “outpatient hospital services” those types of items and services that are not generally furnished by most hospitals in the State.

* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: July 18, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: August 20, 2008.

Michael O. Leavitt,

Secretary.

[FR Doc. E8-26554 Filed 11-6-08; 8:45 am]

BILLING CODE 4120-01-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[DA 08-2330; MB Docket No. 08-98; RM-11435]

Television Broadcasting Services; Honolulu and Waimanalo, Hawaii

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission grants a petition for rulemaking filed by Pacifica Broadcasting Company, permittee of KALO-DT, and Oceania Christian Church, permittee of KUPU-DT, to substitute DTV channel *38 for post-transition DTV channel *10 at Honolulu, Hawaii and DTV channel 15 for post-transition DTV channel 38 at Waimanalo, Hawaii.

DATES: This rule is effective December 8, 2008.

FOR FURTHER INFORMATION CONTACT: Shaun A. Maher, Media Bureau, (202) 418-1600.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's *Report and Order*, MB Docket No. 08-98,

adopted October 21, 2008, and released October 22, 2008. The full text of this document is available for public inspection and copying during normal business hours in the FCC's Reference Information Center at Portals II, CY-A257, 445 12th Street, SW., Washington, DC 20554. This document will also be available via ECFS (<http://www.fcc.gov/cgb/ecfs/>). (Documents will be available electronically in ASCII, Word 97, and/or Adobe Acrobat.) This document may be purchased from the Commission's duplicating contractor, Best Copy and Printing, Inc., 445 12th Street, SW., Room CY-B402, Washington, DC 20554, telephone 1-800-478-3160 or via e-mail <http://www.BCPIWEB.com>. To request this document in accessible formats (computer diskettes, large print, audio recording, and Braille), send an e-mail to fcc504@fcc.gov or call the Commission's Consumer and Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (TTY). This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13. In addition, therefore, it does not contain any information collection burden “for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this Report and Order in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television, Television broadcasting.

■ For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Hawaii, is amended by adding DTV channel *38 and removing DTV channel *10 at Honolulu and by adding DTV channel 15 and removing DTV channel 38 at Waimanalo.