

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 440 and 447

[CMS-2213-P]

RIN 0938-AO17

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

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the regulatory definition of outpatient hospital services for the Medicaid program. Outpatient hospital services are a mandatory part of the standard Medicaid benefit package. The current regulatory definition at 42 CFR 440.20 is broader than the definition in Medicare, and can overlap with other covered benefit categories. The 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 for which Federal financial participation (FFP) is available under the outpatient hospital services benefit category.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 29, 2007.

ADDRESSES: In commenting, please refer to file code CMS-2213-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Submit electronic comments on CMS regulations with an open comment period." (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By regular mail.* You may mail written comments (one original and two copies) to the following address ONLY:

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

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: 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.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7195 in advance to schedule your arrival with one of our staff members: Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

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

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-2213-P and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in

a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: <http://www.cms.hhs.gov/eRulemaking>. Click on the link "Electronic Comments on CMS Regulations" on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Introduction

Title XIX of the Social Security Act (the Act) authorizes the Secretary of the Department of Health and Human Services (the Secretary) to provide grants to States to partially finance programs furnishing medical assistance (State Medicaid programs) to specified groups of needy individuals in accordance with an approved State Plan. "Medical Assistance" is defined at section 1905(a) as payment for part or all of the cost of a list of specified care and services, including at section 1905(a)(2)(A), "outpatient hospital services."

Details concerning the scope of covered services, the groups of eligible individuals, the payment methodologies for covered services, and all other information necessary to assure that the plan can be a basis for Federal Medicaid funding must be set forth in the approved Medicaid State Plan. For approval, the Medicaid State plan must comply with requirements set forth in section 1902(a) of the Social Security Act (the Act), as implemented and interpreted in applicable regulations and guidance issued by the Centers for Medicare & Medicaid Services (CMS). The Secretary has delegated overall authority for the Federal Medicaid program, including State Plan approval, to CMS.

Medicaid services are jointly funded by the Federal and State governments in accordance with section 1903(a) of the Act. Section 1903(a)(1) of the Act provides for payments to States of a percentage of expenditures under the approved State Plan for covered medical assistance. The percentage of Federal financial participation (FFP) is the "Federal Medicaid assistance percentage" (FMAP). For ordinary medical assistance, the FMAP varies

among the States based on a complex formula set forth in section 1905(b) of the Act.

Section 1902(a)(30)(A) of the Act requires a State Medicaid plan to meet certain requirements in setting payment amounts for covered care and services. One of these requirements is that State Plan methodologies must assure that payments are consistent with efficiency, economy, and quality of care. This provision provides authority for specific upper payment limits (UPLs) set forth in Federal regulations in 42 CFR part 447 relating to certain Medicaid covered services. The UPL applicable to outpatient hospital services is at § 447.321.

The purpose of this 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 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.

II. Background

A. Medicaid Outpatient Hospital Services as Currently Defined

Section 1905(a)(2)(A) of the Act lists outpatient hospital services as a benefit that can be covered under a State Medicaid program, and it is among those benefits that is mandatory for the most eligible Medicaid populations under sections 1902(a)(10)(A) and 1902(a)(10)(C)(iv) of the Act. The statute does not provide a definition for these services. The current implementing regulation at § 440.20 describes "outpatient hospital services" as 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; and
- (3) Are furnished by an institution 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) 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.

An "outpatient" is defined in § 440.2(a) as "a patient of an organized medical facility, or distinct part of that facility who is expected by the facility to receive and who does receive professional services for less than a 24-hour period regardless of the hour of admission, whether or not a bed is used, or whether or not the patient remains in the facility past midnight."

Because the regulatory definition of outpatient hospital services is so broad, there is a high possibility of overlap between outpatient hospital services and other covered benefits. This overlap results in circumstances in which payment for services is made at the high levels customary for outpatient hospital services instead of the levels associated with the other covered benefits. For example, there have been instances of claims for payment of physician services as outpatient hospital services, which result in payment far in excess of the rates available in the State for physician services. In addition, the Fifth Circuit Court of Appeals, in *Louisiana Department of Health and Hospitals v. CMS*, 346 F. 3d 571 (2003), found that hospital-based rural health clinic services were within the current definition of outpatient hospital services and, although paid under a separate methodology, could be included in calculating supplemental payments for uncompensated care costs of outpatient hospital services. The result of these overlapping definitions is payment for identical services of a higher amount under the outpatient hospital benefit than otherwise available under the State Plan.

In addition, the current broad definition of outpatient hospital services is not clear on whether outpatient hospital services can include types of services that are outside the normal responsibility of outpatient hospitals, such as practitioner, school-based, and rehabilitative services. In other words, the current broad definition does not clearly limit the scope of the outpatient hospital service benefit to those services over which the outpatient hospital has oversight and control.

Also important, as we discuss further in the following section below, the broad definition of Medicaid outpatient hospital services is inconsistent with the applicable UPL, which is based on the premise of some level of comparability between the Medicare and Medicaid definitions of outpatient hospital and clinic services. The UPL regulation at § 447.321 limits outpatient

service payments to what Medicare would pay for equivalent services. This proposed regulation would clarify the scope of services that may be included in the State Plan definition of outpatient hospital services to clarify coverage and payment requirements for outpatient services.

B. Medicaid Outpatient Hospital Services Upper Payment Limit as Currently Defined

Limitations on aggregate State payments for outpatient hospital and clinic services are established in regulation at § 447.321, "Outpatient hospital services and clinic services: Application of upper limits of payments." This regulation requires that aggregate State Medicaid payments for outpatient hospital and/or clinic services not exceed a reasonable estimate of the amount the provider would be paid under Medicare payment principles, forming a UPL for these services. The aggregate Medicaid payments and corresponding UPL for outpatient hospital and/or clinic services are calculated for private facilities. FFP is not available for State expenditures that exceed the upper payment limit.

Before 1981, States were required to pay rates for hospital and long-term care services that were directly related to Medicare reasonable cost reimbursement. To comply with this requirement, many States set Medicaid hospital rates using reasonable costs as determined by Medicare. The Congress removed the Medicare cost-based reimbursement requirements by enacting legislation in 1980 and 1981, collectively referred to as the Boren Amendment.

Under section 962 of the Omnibus Reconciliation Act of 1980 (ORA 1980), Pub. L. 96-499, and Section 2173 of the Omnibus Budget Reconciliation Act of 1981 (OBRA 1981), Pub. L. 97-85, the Congress provided States flexibility to deviate from Medicare cost determinations for hospital reimbursement. In lieu of using Medicare cost reimbursement rates, States were allowed to set rates based on the costs of efficiently and economically operated facilities.

Though the Boren Amendment removed the specific requirement that States adhere to Medicare cost principles, the legislative history indicates the intent that the Secretary continue to require that payments made to hospitals and other inpatient facilities under the State Plan not exceed Medicare payment principles.

The Senate Finance Committee stated that "the Secretary would be expected

to continue to apply current regulations that require that payments made under State plans do not exceed amounts that would be determined under Medicare principles of reimbursement (S. Rep. No. 471, 96th Cong. 1st Sess. (1979)).” These limitations provide us with the authority to establish UPLs for outpatient and inpatient hospital services.

The Congress allowed for even more flexibility for State payments to hospital and other providers under the Balanced Budget Act of 1997 (BBA), Pub. L. 105–33. The BBA effectively replaced the requirements of the Boren Amendment with a public process to determine the rates of payment under the State Plan. The public process requires that States publish proposed and final rates, the methodologies underlying the established rates, and the justification for the rates. Providers, beneficiaries, and other concerned State residents have an opportunity to review and comment on the rates before they become final.

Section 705 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) required that we publish final regulations authorizing transition periods for States to comply with the UPL regulations. In response to this statutory directive, we modified the UPL regulations for inpatient and outpatient hospital services through a final regulation on January 12, 2001 (66 FR 3147).

In addition, on May 29, 2007 (72 FR 29748), CMS published a final rule (CMS–2258–FC) which will impact the outpatient and inpatient hospital upper payment limits for services provided by units of government. Congress has enacted a one year moratorium that delays CMS from implementing the policies established under that final rule. The provisions proposed in this regulation address completely different policy matters than those set forth in CMS–2258–FC.

The current outpatient hospital UPL regulation prohibits States from paying more, in the aggregate, for Medicaid outpatient hospital services than the “reasonable estimate” that Medicare would pay for equivalent services in privately operated facilities.

As with the scope of outpatient hospital services that may be included under the State Plan, the “reasonable estimate” of what Medicare would pay for equivalent Medicaid services has had varied interpretations. Some States have proposed to use their own hospital cost reports to assess the “reasonable estimate” of Medicare payment. These cost reports may not represent finalized

data or accurately reflect Medicare payment and/or charge rates. To establish standardization across all States, the proposed rule would require States to base the “reasonable estimate” upon service charge ratios reported in the most recently filed Medicare hospital cost report, or a State cost report for which the State can clearly demonstrate gathers data elements directly from the proposed standard worksheets and lines on the most recently filed Medicare cost report. We believe that these standards will provide an accurate resource for the “reasonable estimate” of what Medicare would pay for equivalent Medicaid services.

C. General Intention of Proposed Rule

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

Therefore, as discussed in more detail below, we are proposing to change the definition and scope of outpatient hospital services, and the corresponding UPL for outpatient hospital and clinic services, in an effort to clarify the current regulatory language and make it consistent with the intent of the Congress in enacting section 1905(a)(2)(A) of the Act. This revised definition of outpatient hospital services would align the outpatient services covered by Medicaid with those covered by Medicare. As a result, the calculation of the Medicaid UPLs would reflect a comparison of like services. The revised definition would also narrow the scope of Medicaid outpatient services to those traditionally and typically recognized as outpatient facility services. While we recognize that Medicaid covers certain services that are not covered by Medicare, this regulation would not prohibit States from covering any Medicaid service allowable under section 1905(a) of the Act. Rather, the regulation would only define services that may be covered, and reimbursed, under the outpatient hospital services benefit in the Medicaid State Plan.

In addition, a number of States have requested that we clarify in regulation the requirements for calculating Medicare comparable UPLs on outpatient and clinic services. The current regulation at § 447.321 limits outpatient hospital and rural health clinic payments in privately operated facilities to “a reasonable estimate of the amount that would be paid for services furnished by the group of facilities under Medicare payment principles.”

The current regulation does not address how this estimate should be made, nor does it address the treatment of services that are not comparable to a service furnished under Medicare. As States provide an array of services in a variety of settings authorized under § 440.90, we are proposing to set forth effective UPLs to limit Medicaid payments in all clinic settings.

To address these concerns, as discussed below in more detail, in addition to revising the definition of “outpatient hospital services” for consistency between Medicare and Medicaid, we are proposing changes to address the method for calculating the UPL. The proposed UPL definition of outpatient hospital services and clinics would establish payments as reported on the most recently filed Medicare cost report, or a State cost report for which the State can clearly demonstrate gathers data elements directly from the proposed standard worksheets and lines on the most recently filed Medicare cost report, as the standard for the reasonable estimate of what Medicare would pay for equivalent Medicaid services. The Medicare cost report reflects cost-to-charge ratios for all outpatient services reimbursed prospectively or reimbursed under a fee schedule by Medicare. Additionally, payment-to-charge ratios may be derived from the Medicare cost report for all facility payments reported to the Medicare fiscal intermediary. Medicare regularly updates these payment systems to recover costs for providers.

We believe that the Medicare costs or payments reported in the most recently filed Medicare cost reports, or an equivalent State cost report as described above, provide the most accurate measure of what Medicare would pay for Medicaid-equivalent outpatient hospital services.

D. Medicaid Outpatient Hospital Service Definition

Scope of Outpatient Hospital Services—Proposed Rule

The BBA required CMS (formerly the Health Care Financing Administration) to implement an outpatient prospective

payment system (OPPS) for hospital services reimbursed under the Medicare program. Before the implementation of OPPS, services were reimbursed on a formula-driven basis. As part of the development process for the OPPS, we published a proposed rule on September 8, 1998 (63 FR 47552) that, among other provisions, described the services that would be paid for by Medicare on a prospective basis. The final rule was published in the **Federal Register** on April 7, 2000 (65 FR 18434).

Regulations at 42 CFR part 419—Prospective Payment System for hospital Outpatient Department Services—describes the categories of hospitals and the services that are included and excluded from the Medicare hospital OPPS. The proposed rule references the services that Medicare pays for under the OPPS, defined at § 419.2. In addition, the proposed rule references other outpatient hospital facility services that Medicare pays through an alternate methodology, such as a fee schedule, as coverable Medicaid outpatient hospital services. While Medicare pays for both professional and facility services through alternate payment methodologies, the proposed rule would limit Medicaid coverage and payment for outpatient hospital services to facility services only. For example, States may cover and reimburse prosthetic devices, prosthetics, supplies, and orthotic devices, durable medical equipment, and clinical diagnostic laboratory services as outpatient hospital services.

In addition, the proposed rule would allow States to cover outpatient services provided outside of the hospital only in a department of a provider that meets the standards defined under Medicare regulations in 42 CFR part 413, subpart E—Payments to Providers. This section of the regulations describes the relationship that facilities with provider-based status must have with a hospital in order to receive Medicare payments equivalent to those received by hospitals. Specifically, our intention is to ensure that a department of a hospital that meets the Medicare requirements for provider-based status and is reimbursed for Medicaid outpatient hospital services is treated the same as the main provider. In contrast, a provider-based entity that is not a department of the main provider would be treated as a separate, non-hospital, entity for this purpose (by definition, under 42 CFR 413.65(a)(2), provider-based entities provide health care services of a different type from those of the main provider).

We have considered other options and believe that the services recognized under Medicare regulations as outpatient hospital services represent an industry-accepted class of services. By including services reimbursed to outpatient hospitals under Medicare OPPS and outpatient services reimbursed through Medicare fee schedules within the Medicaid definition, we would provide greater consistency between the two federally funded programs. In addition, we are proposing to adopt Medicare's definition of a department of a provider meeting the requirements of provider-based status, into Medicaid regulation to assure that all providers that are reimbursed for outpatient hospital services have a legal relationship with a main provider that is defined under regulation. This is consistent with efficiency and economy as set forth in section 1902(a)(30)(A) of the Act.

The proposed rule also would exclude States from covering under the Medicaid outpatient hospital benefit services that are covered under another medical assistance service category under the State Plan. Our review of State Plan methodologies recently submitted to CMS finds that States may include non-facility and/or non-traditional hospital services (that is, school-based services and rehabilitation services) within the definition of covered outpatient hospital services. For example, States have proposed including school-based, adult day health and rehabilitative services in the outpatient hospital coverage section of the State Plan. In many cases, these services are already covered and paid for under another methodology under the plan. In at least one instance, a State reimburses non-traditional hospital services at the rate that community providers receive, as defined under the distinct payment methodology for those services under the State Plan, rather than the higher outpatient rate that should be paid for a covered outpatient service.

Such inconsistencies have the potential to enhance the UPL for outpatient services by increasing the scope of outpatient hospital services that might be included in the UPL calculation. We are proposing to exclude non-facility and/or non-traditional hospital services from the outpatient definition in this proposed rule to assure efficiency and economy within the scope of outpatient hospital services as outpatient service rates are generally higher than rates for other Medicaid non-facility services. An outpatient hospital service may not be covered and/or reimbursed under

another Medical Assistance services category under the State Plan. However, States may continue to cover any service that is authorized under section 1905(a) of the Act within the State Plan under a coverage benefit that is distinct from outpatient hospital services.

Finally, the proposed rule would make a clear distinction between outpatient services 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. We are restricting the Medicaid outpatient hospital definition to facility services only to prevent duplicative payments for professional services that are reimbursed under a separate payment methodology, under a different benefit category under section 1905(a) of the Act.

E. Upper Payment Limits—Proposed Rule

We are proposing to revise § 447.321 to clarify the appropriate Medicare references that States may use to derive the reasonable estimate of what would be paid for Medicaid outpatient and clinic services furnished by the group of facilities under Medicare payment principles.

Outpatient Hospital Upper Payment Limit

The revisions to the outpatient UPL, as defined in the proposed rule, would limit the services that may be included in the outpatient hospital UPL for privately operated facilities to those with a Medicare equivalent as reported through the most recently filed Medicare cost report, for each outpatient hospital Medicaid service provider, or a State cost report for which the State can clearly demonstrate gathers data directly from the proposed standardized Medicare cost report references. The proposed rule would allow States to include within the UPL calculation only services that (1) may be covered under the Medicaid outpatient coverage definition; and (2) that show up on outpatient-specific Medicare hospital cost report worksheets. Thus, the scope of outpatient hospital services as defined by Medicaid would be the same services as those included in the outpatient hospital UPL. Though we recognize that Medicaid covers more services than Medicare, we believe that an economic and efficient UPL should include only services to which there exists a Medicare equivalent.

Restricting the permissible scope of Medicaid outpatient hospital services to Medicare's definition would allow us to define standard references that States may use to calculate the UPL. All Medicare-certified institutional providers, including hospitals, are required to submit annual cost reports to a fiscal intermediary. These cost reports include information such as facility characteristics, utilization data, cost and charges by cost center (in total and for Medicare), Medicare settlement data, and financial Statement data. The Medicare hospital cost report captures all of the services that are included in the proposed revised definition of Medicaid outpatient hospital services, and it is the most accurate reflection of what Medicare would pay for Medicaid equivalent services.

As previously stated, the Medicare hospital cost report includes line items that calculate a cost-to-charge ratio (ratio of the provider's actual costs vs. the amount the provider charges). The cost-to-charge ratio on the Medicare cost report captures the highest possible amount that Medicare would pay for an outpatient service. The proposed rule would allow States to use either the cost-to-charge ratio, as reported on the most recently filed Medicare hospital cost report, or a payment-to-charge ratio (the ratio of the amount that Medicare actually pays for outpatient hospital services through the fiscal intermediary vs. the amount of the hospital's charges for such services) to develop the foundation of a reasonable estimate of what Medicare would pay for Medicaid's outpatient hospital services. For either UPL methodology, the dates of service as reported to the Medicare hospital cost report for Medicare cost or payment must match the dates of service for Medicare charges as reported to the cost report.

We currently require that States demonstrate compliance with the UPL for outpatient hospital services using one of the methods described above when the State submits a Medicaid State plan amendment for outpatient services. The UPL demonstration must include a formula that clearly accounts for either the ratio of Medicare cost to Medicare charges multiplied by Medicaid outpatient charges, or the ratio of Medicare payments to Medicare charges multiplied by Medicaid outpatient charges. The State must cite all references from the most recently filed Medicare hospital cost report that are included in the Medicare cost-to-charge ratio or Medicare payment-to-charge ratio portion of the UPL formula. States utilizing a State-specific cost report must demonstrate a clear crosswalk

between the proposed Medicare cost report references that may be included in a UPL demonstration and the State's reporting system.

For a cost-to-charge UPL demonstration, the link to Medicare is made through reference to ancillary and outpatient hospital services cost center cost-to-charge ratios as found on Worksheet C, Column 9, lines 37–68 or Worksheet D, Part V, Column 1.01, lines 37–68 of the CMS 2552–96. These ratios, which must be determined for each provider, include all cost regardless of payer for all ancillary and outpatient cost centers and charges made to all payers including Medicaid. CMS will not accept a UPL that is inflated by adjusting Medicare's allowed cost as reported on these worksheets.

The applicable outpatient hospital service payment references for a payment-to-charge UPL demonstration may be found on Worksheet E, Part B of the CMS 2552–96. While Worksheet E represents what Medicare pays for services within hospitals, States must make certain adjustments in order to reflect equivalent Medicaid outpatient hospital provider services that may be included in the UPL demonstration. For example, all lines that report payments associated with professional services must be removed from the numerator. Additionally, States must ensure that bad debts are not over-reported by including deductibles and coinsurance and reimbursable bad debt in Medicare payments. If deductible and coinsurance are added on to the Medicare payment, the State should remove reimbursable bad debts included in the Medicare payment. The resulting payments reported from Worksheet E should represent allowable Medicare payments for purposes of the UPL demonstration. The source of Medicare charge data, reflected in the ratio's denominator, must come from Worksheet D, Part V and Part VI of the Medicare cost report.

We note that a payment-to-charge ratio UPL methodology may not be inclusive of the full scope of outpatient hospital services because payments and charges on the Medicare cost report do not include payments and charges reimbursed on a fee-for-service basis through the Medicare Part B Carrier. For example, durable medical equipment payments and charges are not included on Worksheets E and D. We believe States should have the flexibility to determine the UPL through a comparison of Medicare payment.

We also note that the specific line references from the Medicare hospital cost report are subject to change as the Medicare cost report and reporting requirements are modified by CMS.

However, only those costs, charges, and payments included in the above worksheets and lines on the CMS 2552–96 (the current standard Medicare hospital cost report form at the issuance of this proposed rule) may be included in the outpatient UPL demonstration for Medicaid services.

Depending on which UPL demonstration methodology the State utilizes, the Medicare cost-to-charge ratio or the Medicare payment-to-charge ratio for each provider, this ratio is multiplied by the Medicaid outpatient hospital charges associated with paid claims for each provider as reported to the Medicaid Management Information System (MMIS). We have considered other methods and believe that the use of adjudicated claims excludes outpatient services paid for by Medicare for patients dually eligible for Medicare and Medicaid and helps to assure that charges represent covered Medicaid services. The Medicaid charge data must exclude clinical diagnostic laboratory services, which are limited to a separate UPL under section 1903(i)(7) of the Act, and all professional services.

The resulting product is an estimate of the actual cost or payment associated with Medicaid outpatient hospital facility services. The total estimate of Medicaid cost or payment is compared to actual Medicaid paid claims to determine whether outpatient hospital payments exceed the UPL.

States may choose to trend the UPL data to the current rate year. Under the proposed rule, we are proposing that all data must be trended uniformly in successive years and use the Medicare Market Basket Index as the trending factor. The State must demonstrate to CMS the effect of the trended data for each successive year from the base year to the current rate year. In addition, the State must demonstrate its methodology for any proposed volume trending.

Clinic Upper Payment Limit

For privately operated clinics that are not providing outpatient hospital services under § 440.20 (those that would not be paid by Medicare in that setting under OPPS or under an alternative outpatient hospital service payment methodology) but instead are covered under the authority of § 440.90, the UPL is the reasonable estimate of what would be paid for clinic services furnished by the group of facilities under Medicare payment principles. In calculating the reasonable estimate of what Medicare would pay for Medicaid clinic services, we must consider Medicare's reimbursement methods for these services.

Medicare does not typically pay for clinic services on the basis of cost as reported by the facility. Rather, through the resource-based relative value (RBRVS) system, used to determine the fee-for-service rate, Medicare recognizes specific clinic costs eligible for reimbursement in a clinic setting. For clinic services, a reasonable estimate of what Medicare would pay for equivalent Medicaid services is the non-facility professional rate for those services.

We propose two options for States to demonstrate compliance with the proposed UPL rule for clinic services provided in privately operated facilities, which requires payment that does not exceed a reasonable estimate of what Medicare would pay for equivalent Medicaid services. A State may choose to limit clinic reimbursement to a percentage, not to exceed 100 percent, of what Medicare pays under the non-facility professional rate for equivalent Medicaid services.

This first option would require States to include language in the State Plan that specifies the percentage of the Medicare facility fee schedule that would be paid for services in clinic settings. If the State pays a percentage of what Medicare pays under a facility-specific fee schedule or the non-facility professional rate and wishes to make supplemental payments up to 100 percent of what Medicare pays, the State must demonstrate per CPT code what Medicare would pay for equivalent Medicaid services. The calculation may be conducted in the aggregate for clinic type or by specific facilities (end-stage renal disease (ESRD), ambulatory surgical center (ASC), etc.). If a State opts to pay 100 percent of what Medicare pays under a facility-specific fee schedule or the non-facility professional rate for equivalent Medicaid services, the State would not have the option of making supplemental payments. However, the State would not be required to submit documentation for a clinic UPL demonstration.

As a second option, a State may develop a fee schedule for Medicaid clinic services, which is not based on the Medicare professional fee schedule. Clinical diagnostic laboratory services may not be included in this demonstration because section 1903(i)(7) of the Act requires that these services not exceed the Medicare fee schedule. For all other clinic services, the State may pay through an encounter rate or a Medicaid specific fee schedule that is not based on Medicare payment principles. Under this option, a UPL demonstration is required to demonstrate that Medicaid clinic reimbursement would not exceed what

Medicare would pay for equivalent services. This demonstration must show a comparison by CPT code of the amount paid by Medicare for equivalent Medicaid services. The calculation may be conducted in the aggregate for clinic type or by specific facilities (ESRD, ASC, etc.). Under the second option, a State may pay more than Medicare for some services or facilities, and less than Medicare for others, as long as the aggregate Medicaid payment is equal to or less than the amount that Medicare would pay in the aggregate.

We include a special provision for dental services provided in clinics for purposes of UPL calculations because we recognize that Medicare does not generally cover dental services. Since there is no Medicare payment for dental services in clinic settings, we allow the State to incorporate the Medicaid State Plan fee schedule rate as the reasonable estimate of what Medicare would pay for dental services. As a result, dental clinic providers are not excluded from the State's aggregate clinic UPL calculation.

III. Provisions of the Proposed Rule

A. Overview

Under our proposal, the outpatient hospital services covered under the Medicaid program would continue to be set forth in regulation under § 440.20. In addition, the UPL requirements for outpatient hospital services would continue to be defined under § 447.321. However, both current definitions would undergo significant revision to clarify the scope of outpatient hospital services recognized by the Medicaid program and to standardize Medicare cost and payment principles as the basis to accurately determine the reasonable estimate of what Medicare would pay for equivalent Medicaid services in a privately operated outpatient facility.

B. General Provisions

The revised definitions would begin with existing § 440.20 that describes outpatient hospital services and rural health clinic services. The definition of rural health clinic services would be revised to apply to all clinic settings. In addition, the existing § 447.321 that describes UPLs for Medicaid services provided in outpatient hospitals and clinics would be revised.

1. Outpatient Hospital Services and Rural Health Clinic Services (Proposed § 440.20)

Existing § 440.20 sets forth definitions for outpatient hospital services and rural health clinic services. We are proposing to change § 440.20(a) to

specify the scope of facility services covered under the Medicaid program. We propose to substitute in § 440.20(a) the term "by an institution" for "in a facility." We believe this term better describes outpatient hospital settings where Medicaid services may be covered.

We proposed to modify the requirements for a participating facility to include those described in § 413.65. Though the current regulation requires that participating facilities meet the requirements for participation in Medicare as a hospital, we included the criteria for provider-based status as a department of an outpatient hospital facility, as described in § 413.65, to recognize all settings where Medicaid outpatient hospital services may be provided. In accordance with § 413.65, a department of a provider must furnish health care services of a same type as those of the main provider under the name, ownership, and administrative and financial control of the main provider.

We proposed to add to the current definition a comprehensive list of the scope of services that may be included under the Medicaid outpatient hospital services benefit. The modified definition allows States to cover outpatient services paid for under the Medicare OPPS and all other outpatient hospital facility services that Medicare pays under a fee schedule. These services are limited only to hospital facility services and exclude all professional services. Professional services may continue to be billed under a separate fee schedule rate. The Medicare provision for OPPS covered services may be found at § 419.2(b).

Finally, we excluded all services, other than outpatient hospital services, that are covered and paid under medical assistance under section 1905(a) of the Act. For example, services paid for under a fee schedule (for example, Federally Qualified Health Centers) or services that are typically covered under a different section of the State Plan (for example, rehabilitative services).

2. Outpatient Hospital and Clinic Services: Application of Upper Payment Limits (Proposed § 447.321)

We propose to modify the existing definition of UPLs for outpatient hospital and clinic services to provide States with clear and accurate guidance on the "reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter." The proposed rule would allow States to include within the UPL

calculation only services that may be covered under the Medicaid outpatient coverage definition and that appear on the Medicare hospital cost report.

All hospitals throughout the nation report cost and charge data through Medicare hospital cost reports. Since these reports reflect Medicare data for all outpatient hospital payments made by Medicare, we require States to reference the Medicare hospital cost reports, or a State cost report for which the State can clearly demonstrate gathers data directly from the proposed standardized Medicare cost report references, when calculating the Medicaid outpatient UPL for privately operated facilities. From the Medicare cost reports, States may use payment-to-charge ratios or cost-to-charge ratios and apply the ratios to Medicaid outpatient hospital charges from the MMIS to determine the outpatient UPL. We base the UPL calculation on Medicare hospital cost reports because we believe they provide the most accurate reflection of what Medicare would pay for equivalent Medicaid outpatient hospital services.

Medicare pays on a different basis for clinic services. These rates incorporate some of the facility costs and are higher than traditional fee schedule payments for professional services. States may continue to calculate the reasonable estimate of what Medicare would pay for equivalent Medicaid clinic services using these rates. However, States must demonstrate a clinic UPL by either specifying a percentage, not to exceed 100 percent, of the Medicare rate that is paid by Medicaid. Or a State can demonstrate that, in the aggregate, Medicaid-specific payment rates that are not directly related to Medicare rates are less than what Medicare would pay based on a comparison of what Medicaid pays by CMS Common Procedure Coding System (CPT) code to the amount paid by Medicare for equivalent Medicaid services.

In addition, Medicare generally does not reimburse for dental services. With this in mind, we added a provision allowing States to use the Medicaid fee schedule rate for dental services to calculate the UPL for such services. This provision would allow dental services to be included in the aggregate clinic UPL calculation, and, thus, allow dental providers to be eligible for supplemental payments. Since Medicare generally does not pay for dental services, we believe this is the best alternative for inclusion of dental services in the clinic UPL calculation.

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 (44 U.S.C. 35).

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Statement

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-04), and Executive Order 13132.

Due to a lack of available data, we cannot determine the fiscal impact of this proposed rule. The proposed rule defines the scope of services that may be reimbursed under the outpatient hospital benefit category covered in the Medicaid State plan. In addition, the rule clarifies the appropriate methods States may use to calculate the Medicaid upper payment limit for those services paid to private service providers. CMS does not intend to eliminate or limit the scope of Medicaid services that are defined under Title XIX of the Act.

We have reviewed the effects of the proposed rule and have determined that it would clarify current vague regulatory language but would not significantly alter current practices in most States. This proposed rule is a proactive attempt to clarify and clearly define regulatory language and prevent over calculation of the outpatient hospital upper payment limit. Therefore, we do not believe the proposed rule would have significant economic effects.

Over the past 4 years, CMS has approved outpatient hospital reimbursement methodologies submitted by 32 States. As part of our review process, we have determined that only one of the 32 States currently defines non-hospital services as part of the outpatient hospital Medicaid State plan service benefit.

Furthermore, with respect to the one State that CMS believes currently includes non-hospital services under the outpatient hospital benefit category, this rule would not impact the rates of payment for these services under the State plan. While the current regulation might permit payment at a higher outpatient hospital payment rate, that State currently pays for such services at the same rate that is paid for such services outside of the outpatient hospital benefit category.

The rule would have an undetermined effect on the aggregate upper payment limit for private outpatient hospital services within the State. As part of the upper payment limit calculation the State includes the non-hospital services. This effectively raises the limit that Medicaid may pay to hospitals. The rule would prevent the State from defining these services as outpatient hospital services and including them in the UPL calculation.

States calculate the UPL, the reasonable estimate of Medicare payment for equivalent Medicaid services, in the aggregate for all Medicaid services provided by all private providers. This total for all providers is reduced by actual Medicaid payments in a rate year to determine a pool of funding that may be distributed as supplemental payments to outpatient hospital providers. Supplemental payments for outpatient hospital services up to the UPL may be distributed to any hospital within the private category. States are not required to equitably distribute supplemental payments among providers or exhaust the available supplemental payment pool.

Considering the UPL is calculated in the aggregate for all outpatient hospital service for all private providers, it is impossible to isolate the exact fiscal impact of removing non-hospital services from the UPL calculation. Even if the payments for these services could be isolated in a particular year, the difference between the reasonable estimate of Medicare payment for a particular service and Medicaid payments for these services could vary drastically from year-to-year as payment amounts for services change within each program. Additionally, the UPL calculation considers the volume of a particular service rendered to Medicaid beneficiaries, which also varies between rate years. Therefore, we cannot determine the exact fiscal impact of removing non-hospital services from the private UPL calculation within this one State.

We believe the fiscal impact would be minimal because most States

historically have not made supplemental payments to private providers up to the upper payment limit. In fact, the State that we suspect could be affected by this rule has recently reported paying approximately \$68 million under the outpatient hospital UPL to private facilities. We do not believe the services that would be removed by this proposed rule would cause such a significant impact on the UPL calculation. We invite public comment on the potential impact of the rule.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize the net benefits (including potential economic, environmental, public health and safety effects, distributive impacts and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). The rule proposes to clarify the definition of outpatient hospital services and the UPL for these services to provide additional guidance to States that interpret these definitions. Under the revised regulations, States would not be prevented from covering Medicaid services under the State Plan. Rather, a few States may need to move services that are not outpatient in nature, as defined by Medicare, to the appropriate coverage and payment methodology in the State Plan. With this in mind, the rule would not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for this RFA because we have determined that this rule would not have a significant economic impact on a substantial number of small entities.

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 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of

a Metropolitan Statistical Area and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. The proposed rule would not prevent States from receiving FFP for Medicaid covered services. Therefore, the net change in appropriate FFP that can be received by States for Medicaid expenditures is economically insignificant. The proposed rule would not result in anticipated costs or benefits to the private sector.

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 on State and local governments, preempts State law, or otherwise has Federalism implications. Because the proposed rule seeks to curb inappropriate Federal revenue maximization, the proposed rule would not impose any additional costs to States. Again, States may receive FFP for all appropriate Medicaid expenditures for covered services.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 440

Grant programs—health, Medicaid.

42 CFR Part 447

Accounting, Administrative practice and procedure, Drugs, Grant programs—health, Health facilities, Health professions, Medicaid, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services would amend 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 clinic and hospital facility 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 an outpatient hospital 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.

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PART 447—PAYMENTS FOR SERVICES

3. The authority citation for part 447 continues to read as follows:

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

4. Section 447.321 is amended by revising paragraphs (a) and (b) to read as follows:

§ 447.321 Outpatient hospital and clinic services: Application of upper payment limits.

(a) *Scope.* This section applies to rates set by the agency to pay for outpatient services furnished by hospitals and clinics within one of the following categories:

- (1) State government operated facilities (that is, all facilities that are operated by the State) as defined at § 433.50(a) of this chapter.

(2) Non-State government operated facilities (that is, all governmentally operated facilities that are not operated by the State) as defined at § 433.50(a) of this chapter.

(3) Privately operated facilities that is, all facilities that are not operated by a unit of government as defined at § 433.50(a) of this chapter.

(b) *General rules.* (1) For privately operated facilities, upper Payment Limit (UPL) refers to a reasonable estimate of the amount that would be paid for the services furnished by the group of facilities under Medicare payment principles in subchapter B of this chapter.

(i) *Private Outpatient Hospital Services.* Services included in the calculation of the private outpatient hospital UPL must meet all of the criteria for outpatient hospital services defined in § 440.20 of this chapter. A reasonable estimate of the amount that would be paid for outpatient hospital services under Medicare payment principles is determined through—

(A) Calculation of estimated Medicare payment for Medicaid equivalent outpatient services reimbursed under current Medicare payment systems, including—

(1) Outpatient hospital services paid under the Medicare outpatient prospective payment system as defined under § 419.2 of this chapter; and

(2) Outpatient hospital services or clinic services paid under a Medicare outpatient hospital or clinic fee schedule or alternate payment methodology.

(B) The estimated Medicare payment may be based on the Medicare cost report, or an accepted State cost report that reports the same data from the Medicare cost report references in paragraphs (b)(1)(i)(B)(1) through (b)(1)(i)(B)(2) of this section, as the source to determine either:

(1) The ratio of costs-to-charges for all services included in the outpatient hospital UPL calculation. The Medicare cost-to-charges ratios for outpatient hospital services are found on Worksheet C and Worksheet D, Part V of the Medicare cost report; or

(2) The ratio of payments-to-charges for all services included in the outpatient hospital UPL calculation. Medicare outpatient payments are found on Worksheet E, Part B and outpatient charges are found on Worksheet D, Part V of the Medicare cost report.

(3) The charge ratios in paragraphs (b)(1)(i)(B)(1) through (b)(1)(i)(B)(2) of this section for Medicare equivalent services are multiplied by Medicaid charges as reported to the Medicaid

Management Information System (MMIS).

(ii) *Private Clinic Services.* For privately operated clinics that are not providing outpatient hospital services under § 440.20 (those that would not be paid by Medicare in that setting under OPPTS or under an alternative outpatient hospital service payment methodology), the reasonable estimate of what Medicare would pay for equivalent Medicaid services may be determined through:

(A) A State Plan reimbursement methodology for covered services that is a defined percentage, not to exceed 100 percent, of what Medicare pays under the non-facility fee schedule; or

(B) For reimbursement methodologies based upon a Medicaid-specific fee schedule or encounter rate, a comparison by CPT code of the amount paid by Medicare for equivalent Medicaid services. The calculation may be conducted in the aggregate for clinic type or by specific facilities (ESRD, ASC, etc). Clinical diagnostic laboratory services or any other services for which the Act defines a separate upper limit for Medicaid reimbursement must be excluded from the clinic UPL.

(C) For dentists providing services in clinics, the clinic UPL calculation may include payment amounts at the amount that Medicaid would pay outside of the facility.

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

Dated: March 15, 2007.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: June 20, 2007.

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on September 24, 2007.

[FR Doc. E7-19154 Filed 9-27-07; 8:45 am]

BILLING CODE 4120-01-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 070827484-7485-01]

RIN 0648-AV99

Fisheries of the Northeastern United States; Recreational Management Measures for the Summer Flounder Fishery; Fishing Year 2008

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes coastwide summer flounder recreational management measures to administratively complete the rulemaking process initiated in March 2007. This action is necessary to propose appropriate coastwide management measures to be in place on January 1, 2008, following the expiration of the current state-by-state conservation equivalency management measures on December 31, 2007. The intent of these measures is to prevent overfishing of the summer flounder resource during the interim between the aforementioned expiration of the 2007 recreational measures and the implementation of measures for 2008.

DATES: Comments must be received by 5 p.m. local time, on October 15, 2007.

ADDRESSES: You may submit comments by any of the following methods:

- E-mail: 0648-AV99@noaa.gov.

Include in the subject line the following identifier: "Comments on 2008 Summer Flounder Interim Recreational Measures."

- Federal e-rulemaking portal: <http://www.regulations.gov>

- Mail: Patricia A. Kurkul, Regional Administrator, NMFS, Northeast Regional Office, One Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope: "Comments on 2008 Summer Flounder Interim Recreational Measures."

- Fax: (978) 281-9135.

Copies of the Supplemental Environmental Assessment, as well as the original Environmental Assessment, Regulatory Impact Review, and Initial Regulatory Flexibility Analysis (EA/RIR/IRFA) completed for the 2007 recreational management measures are available from Daniel T. Furlong, Executive Director, Mid-Atlantic Fishery Management Council, Room