smoking areas will be closed effective June 19, 2009. This six-month phase-in period is designed to establish a fixed but reasonable time for implementing this policy change. This phase-in period will provide agencies with time to comply with their obligations under the Federal Service Labor-Management Relations Act, as amended, 5 U.S.C. Ch. 71, Labor-Management Relations, in those circumstances where there is an exclusive union representative for the employees.

§ 102–74.330 What smoking restrictions apply to outside areas under Executive branch control?

Effective June 19, 2009, smoking is prohibited in courtyards and within twenty-five (25) feet of doorways and air intake ducts on outdoor space under the jurisdiction, custody or control of GSA. This six-month phase-in period is designed to establish a fixed but reasonable time for implementing this policy change. This phase-in period will provide agencies with time to comply with their obligations under the Federal Service Labor-Management Relations Act, as amended, 5 U.S.C. Ch. 71, Labor-Management Relations, in those circumstances where there is an exclusive union representative for the employees.

§ 102–74.335 Who is responsible for furnishing and installing signs concerning smoking restrictions in the building, and in and around building entrance doorways and air intake ducts?

Federal agency building managers are responsible for furnishing and installing suitable, uniform signs in the building, and in and around building entrance doorways and air intake ducts, reading ''No Smoking,'' ''No Smoking Except in Designated Areas,'' ''No Smoking Within 25 Feet of Doorway,'' or ''No Smoking Within 25 Feet of Air Duct,'' as applicable.

§ 102–74.340 Who is responsible for monitoring and controlling areas designated for smoking by an agency head and for identifying those areas with proper signage?

Agency heads are responsible for monitoring and controlling areas designated by them under § 102–74.320(d) for smoking and identifying these areas with proper signage. Suitable, uniform signs reading ''Designated Smoking Area'' must be furnished and installed by the occupant agency.

§ 102–74.345 Does the smoking policy in this part apply to the judicial branch?

This smoking policy applies to the judicial branch when it occupies space in buildings controlled by the executive branch. Furthermore, the Federal Chief Judge in a local jurisdiction may be deemed to be comparable to an agency head and may establish exceptions for Federal jurors and others as provided in § 102–74.320(d).

§ 102–74.350 Are agencies required to meet their obligations under the Federal Service Labor-Management Relations Act where there is an exclusive representative for the employees prior to implementing this smoking policy?

Yes. Where there is an exclusive representative for the employees, Federal agencies must meet their obligations under the Federal Service Labor-Management Relations Act, 5 U.S.C. Ch. 71, Labor-Management Relations, prior to implementing this section. In all other cases, agencies may consult directly with employees.

§ 102–74.351 If a state or local government has a smoke-free ordinance that is more strict than the smoking policy for Federal facilities, does the state or local law or Federal policy control?

The answer depends on whether the facility is Federally owned or privately owned. If the facility is Federally owned, then Federal preemption principles apply and the Federal policy controls. If the facility is privately owned, then Federal tenants are subject to the provisions of the state or local ordinance, even in the Federally leased space, if the state or local restrictions are more stringent than the Federal policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS–2234–F]

RIN 0938–A045

Medicaid Program; State Option To Establish Non-Emergency Medical Transportation Program

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

ACTION: Final rule.

SUMMARY: This final rule implements section 6083 of the Deficit Reduction Act of 2005, which provides States with additional State plan flexibility to establish a non-emergency medical transportation (NEMT) brokerage program, and to receive the Federal medical assistance percentage matching rate. This authority supplements the current authority that States have to provide NEMT to Medicaid beneficiaries who need access to medical care, but have no other means of transportation.

DATES: *Effective date:* These regulations are effective January 20, 2009.

FOR FURTHER INFORMATION CONTACT: Fran Crystal (410) 786–1195.

SUPPLEMENTARY INFORMATION:

I. Background

A. General

For more than a decade, States have asked for the tools to modernize their Medicaid programs. The enactment of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171, February 8, 2006) provides States with new options to create programs that are more aligned with today's Medicaid populations and the health care environment. Cost sharing, benefit flexibility through benchmark plans, health opportunity accounts (HOA), and the flexibility to design cost-effective transportation programs provide opportunities to modernize Medicaid, make the cost of the program and health care more affordable, and expand coverage for the uninsured.

B. Statutory Authority

Section 6083 of the DRA amended section 1902(a) of the Social Security Act (the Act) by adding a new section 1902(a)(70), which allows States to amend their Medicaid State plans to establish a non-emergency medical transportation (NEMT) brokerage program without regard to statutory requirements for comparability, state-wideness, and freedom of choice. This final regulation sets out provisions for implementing the brokerage programs which are within the flexibility granted by the statute.

II. Provisions of the Proposed Rule

A. Overview

The Department of Health and Human Services (DHHS) began issuing guidance about the new flexibilities available to States within months of the enactment of the DRA. On March 31, 2006, DHHS issued a State Medicaid Director letter providing guidance on the implementation of section 6083 of the DRA. We issued an NPRM on August 24, 2007 (72 FR 48604). This proposed regulation proposed, among other things, to formalize the guidance issued on NEMT programs. The proposed regulation would add a new paragraph (4) to 42 CFR 440.170(a).

B. Requirements for State Plans

Under § 431.53, States are required in their title XIX State plans to ensure necessary transportation of Medicaid beneficiaries to and from providers. Expenditures for transportation may be claimed as administrative costs, or a State may elect to include transportation as medical assistance under its State Medicaid plan.

Before enactment of the DRA, if a State wanted to provide transportation as medical assistance under the State plan, it could not restrict beneficiary choice by selectively contracting with a broker, nor could it provide services differently in different areas of the State without receiving, under section 1915(b) of the Act, a waiver of freedom of choice, comparability, and state-wideness otherwise required by section 1902(a) of the Act. These waivers allowed States to selectively contract with brokers and to operate their programs differently in different areas of the State.

The DRA gives the States greater flexibility in providing NEMT. States are no longer required to obtain a section 1915(b) waiver in order to provide NEMT as an optional medical service through a competitively contracted broker. A State plan amendment for such a brokerage program eliminates the administrative burden of the 1915(b) biannual waiver renewal. Under new section 1902(a)(70) of the Act, a State may now use a NEMT brokerage program when providing transportation as medical assistance under the State plan, notwithstanding the provisions of sections 1902(a)(1), 1902(a)(10)(B), and 1902(a)(23) of the Act, concerning state-wideness, comparability, and freedom of choice, respectively.

Current regulations provide that when a State includes transportation in its State plan as medical assistance, it is required to use a direct vendor payment system that is consistent with applicable regulations at § 440.170(a)(2), and it must also comply with all other requirements related to medical services, including freedom of choice, comparability, and state-wideness. To implement the provisions of section 1902(a)(70) of the Act, we proposed revising § 440.170(a) to add a new paragraph (4), ''Non-emergency medical transportation brokerage program,'' to reflect the increased flexibility allowed by the DRA.

We proposed allowing, at the option of the State, the establishment of a NEMT brokerage program. We believe that this may prove to be a more cost-effective way of providing transportation for individuals eligible for medical assistance under the State plan, who need access to medical care or services, and have no other means of transportation.

As provided by the statute, we proposed specifying in § 440.170(a)(4) that the broker could provide for transport services that include wheelchair vans, taxis, stretcher cars, bus passes, tickets, secured transportation and other forms of transportation otherwise covered under the State plan. We interpreted ''secured transportation'' at section 1902(a)(70)(A) of the Act to mean a form of transportation containing an occupant protection system that addresses the safety needs of disabled or special needs individuals.

The DRA also provides that other forms of transportation may be included as determined by the Secretary to be appropriate. We did not propose to determine any additional transportation services to be generally appropriate. However, as noted above, we proposed to allow States to identify additional transportation alternatives that were otherwise covered under the State plan and which were not limited to services already available through transportation brokers. We proposed to review these alternatives in the State plan amendment approval process for transportation services generally. In that process, we proposed that CMS would consider the individual circumstances in the State and apply utilization controls as necessary. For example, air transportation could be appropriate in States with significant rural populations and low population density, but not in other States. Even in those States, air transportation might only be suitable with appropriate utilization controls. Thus, we proposed to make this determination in the context of our review of State plan amendments based on the information furnished by the State.

At § 440.170(a)(4), we proposed that the competitive bidding process be consistent with applicable DHHS regulations at 45 CFR 92.36, based on the State's evaluation of the broker's experience, performance, references, resources, qualifications and cost, and that the contract with the broker include oversight procedures to monitor beneficiary access and complaints, and ensure that transport personnel are licensed, qualified, competent, and courteous. We proposed that State and local bodies that wish to serve as brokers compete on the same terms as non-governmental entities.

We proposed in paragraph § 440.170(a)(4)(ii) to include prohibitions on broker self-referrals and conflict of interest, based on the prohibitions on physician referrals under section 1877 of the Act (42 U.S.C. 1395(nn)). Section 1877 of the Act generally prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies. In addition, to prevent other types of fraud and abuse, the anti-kickback provisions in section 1128B(b) of the Act (42 U.S.C. 1320a-7b(b)) and the provisions in the civil False Claims Act (31 U.S.C. 3729) also would apply to this transportation program as they apply to the Medicaid program generally.

We believe the statute provides that section 1877 of the Act and the applicable regulations be used as a model for establishing broker prohibitions on referrals, conflicts of interest, and impermissible kickbacks, in order to prevent fraud and abuse.

As we stated in the proposed rule, a financial relationship, as defined in the regulations implementing section 1877 of the Act at § 411.354(a), includes any direct or indirect ownership or investment interest in an entity that furnishes designated health services and any direct or indirect compensation arrangement with an entity that furnishes designated health services (DHS).

Section 1877 of the Act includes exceptions to certain ownership, investment, and compensation arrangements. In addition, section 1877(b)(4) of the Act allows the Secretary to create an exception in the case of any other financial relationship that does not pose a risk of program or patient abuse.

For purposes of new § 440.170(a)(ii)(A), we proposed that the term ''transportation broker'' include contractors, owners, investors, Boards of Directors, corporate officers, and employees.

We proposed to use the definition of ''financial relationship'' as set forth in regulations at § 411.354(a) by means of cross-reference, with the term ''transportation broker'' substituted for ''physician'' and ''non-emergency transportation'' substituted for ''DHS.'' We proposed to use the definition of ''immediate family member'' or ''member of a physician's immediate family'' as set forth in the physician self-referral provisions in § 411.351, with the term ''transportation broker'' substituted for ''physician.''

Based on the prohibitions in section 1877 of the Act, we proposed that the broker be an independent entity, in that the broker could not itself provide transportation under the contract with the State and that the broker could not refer or subcontract to a transportation service provider with which it has certain financial relationships, unless certain exceptions applied. Federal funds could not be used for any prohibited referrals.

Similar to some of the ownership exceptions in section 1877 of the Act, we proposed including exceptions for a non-governmental broker that provided transportation in a rural area (as defined in § 412.62(f)(1)(iii)) when there was no other qualified provider available; when the necessary transportation provided by the non-governmental broker was so specialized that no other qualified provider was available; or when the availability of qualified providers other than the non-governmental broker was insufficient to meet the existing need.

For purposes of this regulation we proposed that a qualified provider would be any Medicaid participating provider or other provider determined by the State to be qualified. A ''rural area,'' as defined in § 412.62(f) (1)(iii), is any area that is outside an urban area. An ''urban area'' is defined in § 412.62(f)(1)(ii). These exceptions would address specific circumstances in which there was a lack of transportation resources and there was documentation to support these exceptions.

Governmental Brokerages

We did not wish to prevent a government entity that was awarded a brokerage contract through the competitive bidding process from referring an individual in need of transportation service to a government transportation provider that was generally available in the community. Therefore we proposed to include an exception to allow such a governmental broker to provide an individual transportation service or to arrange for the individual transportation service by referring to or subcontracting with another government-owned or controlled transportation provider, when certain conditions were met that would assure an arms-length transaction.

The broker would first be required to be a distinct governmental unit, and the contract could not include payment of costs other than those unique to the distinct brokerage function. This means that the contract could not provide for payment of costs normally shared with or paid by other governmental units (such as a regional transportation authority). This requirement would ensure that the distinct broker unit did not have direct financial conflicts of interest resulting from commingling funding with State or local general revenue funds. Second, the broker would have to document, after considering the specific transportation needs of the individual, that the government provider was the most appropriate, effective, and lowest cost alternative for each individual transportation service. Third, the broker would have to document that for each individual transportation service, the Medicaid program was paying no more than the rate charged to the general public. Because there could still be conflicts of interest resulting from management oversight from a parent or related governmental unit, we considered proposing to limit the exception to circumstances where the distinct unit governmental broker was independent of external review and oversight by the parent entity. However, we believe that the proposed conditions will be sufficient to protect against inappropriate inter-governmental referrals.

We solicited comments, suggestions, and examples regarding the following exceptions mentioned above: The service area is rural and there is no other Medicaid participating or qualified provider available except the non-governmental broker; the transportation provided by the non-governmental broker is so specialized that no other qualified provider is available (including comments on how ''specialized'' should be defined); available qualified providers other than the non-governmental broker are insufficient to meet the need; the broker is a distinct government unit and is paid only for costs that are unique to the distinct brokerage function and the broker documents that services provided by any other governmental entity are the most appropriate, least costly alternative, and the Medicaid program is paying no more than the rate charged to the public.

Additionally, we proposed to include a prohibition on a broker accepting any form of remuneration or payment from a transportation provider in exchange for influencing a referral or subcontract for transportation services. We also proposed that in referring or subcontracting with transportation providers, the broker be prohibited from withholding necessary transportation from a recipient or providing transportation that was not the most appropriate and cost-effective means of transportation.

Under section 1905(a)(28) of the Act, the Secretary is given the authority to specify any other medical care which can be covered by the State. We therefore proposed using this authority to make Federal financial participation available at the medical assistance rate for the cost of the brokerage contract, providing that such a contract complied with the requirements set forth in this regulation.

In accordance with Federal requirements in sections 1902(a)(2) and 1903(w) of the Act and applicable Federal regulations described at § 433.50 through § 433.74, under the brokerage contract with the State Medicaid agency, the non-Federal share of the Medicaid payments made for operating a transportation brokerage program could only be derived from permissible sources and would have to comply with the applicable statute and regulations cited above. Also, the return of any Medicaid payments (directly or indirectly) to a State or local government entity under the NEMT brokerage program would be prohibited.

We proposed that the State, in contracting with the broker, would be required to specify that violation of these provisions would be deemed to be a breach of contract and that the State could move to terminate the contract with the broker.

III. Analysis of and Response to Public Comments on the Proposed Rule

We received a total of 63 timely items of correspondence that raised many different issues. Many of the commenters represented State and local transportation agencies, regional transportation programs, non-profit and for-profit transportation providers, and national associations that represent various aspects of the transportation industry. The remaining comments were from individuals, medical associations and hospitals, human services agencies, and advocacy groups. A summary of the issues and our responses follow:

General Comments: Many commenters praised us for establishing a process which is consistent with the requirements set forth in section 6083 of the DRA of 2005 and which will facilitate the establishment of NEMT brokerage arrangements for State Medicaid programs. Many commenters also praised the overall flexibility provided to States in developing cost-effective quality transportation programs. However, many commenters raised concerns about other aspects of the proposed regulation. A summary of the public comments we received and our responses to the comments are set forth below.

Comments related to paperwork and other burdens are addressed in the Collection of Information Requirements and Regulatory Impact Statement sections in this preamble.

Comment: Several commenters said that the regulation required States to establish a brokerage program, and one commenter objected to CMS requiring States to establish a transportation brokerage because a transportation brokerage is counterproductive, costly and conflicts with the appropriate Federal and State roles of the Medicaid Federal/State partnership. Some commenters suggested that CMS clarify in the final rule that this regulation and the new transportation brokerage option applies only to transportation brokerages when a State chooses to adopt this new flexibility provided by section 6083 of the DRA and the regulation does not apply to the other options States have for assuring the availability of transportation to access Medicaid services.

Response: We wish to clarify that this final rule applies only to transportation brokerages when a State chooses to adopt this new flexibility provided by section 6083 of the DRA. In enacting section 6083 of the DRA, the Congress acted to supplement the current authority that States have to provide NEMT to Medicaid beneficiaries by adding an additional option for providing a NEMT brokerage program under State plan authority. Neither the statute nor this final rule requires States to select this new option. States continue to have the flexibility to provide NEMT as an administrative expense or as an optional medical service. States that wish to establish a NEMT brokerage program without being required to comply with the prohibitions against self-referral, or general Medicaid requirements such as freedom of choice, comparability and state-wideness may continue to do so through the 1915(b) waiver process. The requirements of this final rule apply only to those States that have chosen to obtain State Plan authority to provide NEMT as a medical service through a broker.

Comment: Most of the comments on prohibitions came from regional transportation associations or transportation providers. These commenters disagreed with the prohibition on the broker itself providing transportation, or making a referral to or subcontracting with a transportation provider with which it has a financial relationship. Several commenters asserted that this prohibition was not practical and would limit the number of entities that could bid on a brokerage contract or the number of participating providers. Further, the commenters declared that these prohibitions could possibly limit competition to for-profit brokers, reduce State flexibility in designing the Medicaid transportation program. Moreover, CMS was applying the principles of section 1877 of the Act too broadly and in a way that was not meaningful or useful to States. Some commenters said that CMS' interpretation of the DRA was not consistent with the intent of the DRA itself because the proposed conflict of interest language was being applied in a way that is not in the best interest of the overall management of the NEMT program. A commenter also said that a broker providing transportation is not analogous to a physician making referrals for certain designated health services because the organizational set-ups of the two are vastly different, and unlike physicians, profit is not a concern for governmental transportation agencies.

Several commenters said that the unintended consequence of restricting a company from both managing and providing transportation services would be the creation of an anti-business climate that would likely force already efficient and effective transportation agencies into choosing between the ''broker role'' and the ''provider role,'' and could potentially leave one of these roles unfilled.

Response: In enacting section 6083 of the DRA, the Congress responded in part to public concern that ownership by the broker of a company that provides transportation may result in higher costs and a greater potential for fraud and abuse. Therefore, the Congress looked to recognized prohibitions against self-referral under section 1877 of the Act to guide the Secretary in establishing safeguards against conflict of interest and fraud and abuse. The Congress expressly directed the Secretary to develop requirements for brokers that are similar to the prohibitions on self-referral and conflict of interest that are found under section 1877 of the Act.

Generally, section 1877 of the Act prohibits physicians from making referrals for certain designated health services payable by Medicare to an entity with which the physician or the physician's immediate family has a financial relationship, unless an exception applies. In some cases brokers who own or partly own provider companies may be actively involved in the businesses, while in other cases they may merely be passive investors. Nevertheless, these relationships constitute a conflict of interest because of the potential for fraud and abuse. As in similar physician cases, brokers that also provide transportation could possibly over-utilize higher cost services provided by their own transport companies or possibly bill for services that did not occur. It is this potential for fraud and abuse that these prohibitions have been designed to limit.

While the business of medicine and the business of providing transportation are not necessarily the same, we disagree that physician referral prohibition rules cannot be applied to transportation brokers. We can identify a number of operational similarities between physicians and brokers that justify our decision to include several prohibitions and exceptions. Similar to a physician who refers patients for medical services brokers refer beneficiaries for transportation services. In both cases the potential for over-utilization, inflated costs, and fraudulent billing is higher when the individual (be it a physician or broker) making the referral is allowed to refer to a service owned or partially owned by the individual.

Understanding that there are circumstances where there may be an insufficient number of available providers, we adopted exceptions similar to those in section 1877 of the Act and created exceptions where there are insufficient transportation resources. Under these exceptions, a non-governmental entity awarded a brokerage contract through the competitive bidding process will be permitted to provide transportation in order to meet access requirements. Similarly, we have created exceptions for governmental brokers that we believe will also guard against conflict of interest. We also understand that some rural areas may be underserved and we have created an exception to allow the broker to either use or create its own resources in order to assure that all beneficiaries have access to necessary medical services. Furthermore, we do not agree that the prohibitions would create an anti-business environment, but instead, we believe that such prohibitions would actually level the playing field and promote competition.

Comment: Several commenters disagreed with the prohibition on non-governmental broker self-referral unless the broker can prove that there is no other qualified provider available. One commenter felt that the exceptions should not be permanent because the capacity of other providers may increase over time. One commenter stated that, in general, the proposed rule provided

sound rules for State Medicaid brokerage programs. However, the commenter thought that the conflict of interest provisions were overly broad and suggested that the provisions be modified as follows: (1) The broker should be permitted the discretion to use its own resources or refer to another provider with which it has a financial relationship when deemed necessary by the broker to provide timely, cost-effective and quality transportation, or to otherwise protect the health and welfare of the beneficiary; (2) the broker should be subject to a 10% limit on self-referral in a calendar month, except during the first 90 days of the brokerage contract, when there should be no limit on broker self-referral.

Response: We do not agree with the suggestion that the broker be given blanket discretion to use its own resources or to refer to another provider in which it has a financial interest when deemed necessary by the broker to comply with the contractual requirements of timeliness, cost-effectiveness and quality. Allowing the broker unlimited discretion would be contrary to the prohibitions on self-referral that we believe are required by the statute, and could create opportunities for conflict of interest. We recognize that due to unforeseen circumstances a gap may occur in the provider network from time to time. However, should such a gap occur, we expect the State to: Determine when the broker may temporarily step in to fill such a gap; assure that insufficiencies in the provider network are not chronic or lengthy; and assure that the broker is fulfilling its contractual obligation to maintain an adequate network of available qualified contracted providers. We also expect the State to provide sufficient oversight to ensure that when contracting with transportation providers the broker does not offer reimbursement that is so low that local transportation providers are unwilling to participate, thus creating a need for the broker to provide the transportation itself.

Allowing the broker to self-refer no more than 10 percent of the time during a calendar month or to self refer an unlimited number of times during the first 90 days of the brokerage contract would not achieve the purpose of the prohibition against self-referral. By the starting date of the brokerage program the broker must have a contracted network of providers that is sufficient to provide adequate access for beneficiaries, and the broker should also be ready to meet all other requirements of the contract with the State.

Comment: One commenter wrote that the final rule should include other exceptions found in the Stark regulation so that ''innocent and appropriate'' financial relationships between a broker and a NEMT provider do not preclude the provider from participating in the network. The commenter also suggested that the final rule include provisions that allow the broker to have a contract with a NEMT provider for a line of business that is unrelated to the NEMT brokerage business, such as: Rental of space and equipment; personal services arrangements; payments for bona fide services; fair market value compensation arrangements; risk sharing arrangements; compliance training; indirect compensation arrangements; community wide health information systems; charitable donations; and isolated transactions, found at § 411.357(a), (b), (d), (f), (i), (j), (l), (n), (o), (p), and (u), and exceptions for publicly traded securities and mutual funds at § 411.356(a) and § 411.356(b). The commenter also requested that the final rule address the scenario in which the broker also provides emergency medical transportation (EMS) in the same community in which it acts as a NEMT broker. The commenter requested that the broker explicitly be permitted to provide NEMT services or make a referral to another transportation service provider even though a financial relationship for EMS services existed between the parties.

Response: We considered the commenters' suggestion that we include in the final rule additional exceptions for certain kinds of financial relationships similar to those found at § 411.356 and § 411.357. We are very concerned about financial relationships that may directly or potentially affect the financial interests that are attributed to either the broker or the subcontracted provider. Compensation relationships such as leasing agreements and contracts for similar lines of business between the broker and a potential subcontracted transportation provider, although seemingly innocent or unrelated, may pose the risk of program abuse. Therefore, in this final rule we have decided not to change the prohibitions or exceptions found in the NPRM.

Comment: Many of the commenters believed that the proposed rule contravenes the policies, concepts, and principles of Executive Order 13330 and the Interagency Coordinating Council on Access and Mobility (CCAM), which stresses the importance of coordination of public transportation at the Federal level. These commenters argued that the proposed rule would defeat the efforts of the CCAM and United We Ride to coordinate transportation. A number of commenters also stated that the proposed rule was inconsistent with the statutory creation of a locally-developed, coordinated public transit human service transportation planning process established by the Safe, Accountable, Flexible, Efficient Transportation Equity Act (SAFETEA–LU), Public Law 109–59 (codified at 49 U.S.C. sections 5301, *et seq.*) and carried out by the Federal Transit Administration (FTA). These commenters suggested that CMS withdraw the proposed rule and submit the matter to the Federal Interagency Transportation Coordinating Council on Access and Mobility (CCAM) and United We Ride program to ensure that the new CMS rulemaking is consistent with CCAM policy and the United We Ride Program initiatives.

Response: Executive Order 13330 (69 FR 9185, February 24, 2004) stresses the importance of coordination of public transportation at the Federal level. However, it does not direct Federal agencies to ignore the policies and rules of their particular programs in order to do so. For programs such as Medicaid, the policies of the CCAM are appropriate as long as they do not conflict with the policies and rules of the Medicaid program. The provisions of the proposed rule did not preclude State Medicaid agencies from participating in efforts to coordinate the use of transportation resources consistent with the guidance issued by the CCAM, as long as those coordination efforts recognize that the Medicaid program's responsibility is limited to ensuring cost-effective transportation for beneficiaries to and from Medicaid providers.

In terms of financing, Medicaid is not responsible for the general operation or deficit financing of public or private transportation providers. Medicaid is a joint federal-state financed program. Federal Medicaid funding must be matched by non-federal funding unless there is express authority under federal law for other federal funds to be used for purposes of the non-federal Medicaid matching share, and no such Medicaid authority currently exists. We understand that the FTA SAFETEA–LU statutory language at 49 U.S.C. 5310, 5311, 5316, and 5317 allows States to use Federal Medicaid dollars to fulfill State requirements to draw down Federal transportation grant funds. In that circumstance however, where Federal Medicaid matching funds are included as State match when drawing down FTA grants, Federal Medicaid

funding would not be available to match the part of any future State expenditures funded by the SAFETEA–LU grant because federal statutes authorizing the SAFETEA–LU grant program do not expressly authorize use of SAFETEA–LU funds for matching other federal funds.

Comment: Many commenters felt that if the proposed rule were implemented it would interfere with a State's ability to develop coordinated transportation services. Some commenters suggested that there needs to be a special section of the regulation that deals with coordinated transit services, that States that have rural regional transit agencies need to conceptualize an efficient mechanism to bring Medicaid into coordinated service, and that NEMT brokerages for coordinated rural regional systems should be allowed to reside with the rural regional transit system providing the regional transit agency can show that the total cost to Medicaid is significantly reduced by parallel coordinated service contracts with other human services agencies. One commenter said that human service transportation would be reduced if Medicaid were to be taken out of the coordination mix. One State transportation agency objected to any requirement that the brokerage function be devoted exclusively to Medicaid funded transportation. Another State Transportation Department suggested that CMS add language to the final rule that includes as a criterion for selecting the broker consideration of the benefits of a coordinated transportation system.

Response: The statute did not specifically address coordinated transportation. Coordination of transportation services is a positive goal and we encourage States to develop coordinated transportation systems in order to promote efficiency and cost-effectiveness. However, it should be noted that Medicaid funds may only be used for Medicaid services provided to eligible beneficiaries. When administering the Medicaid NEMT program, States must comply with all applicable Medicaid policies and rules regardless of whether the Medicaid rules interfere with their ability to coordinate their transportation efforts.

Comment: Many commenters disagreed with the requirement for governmental brokers to document with respect to the individual's specific transportation needs that the government provider is the most appropriate and lowest cost alternative, and that the Medicaid program is paying no more than the rate charged to the general public. The commenters said that the documentation requirement will result in additional and costly recording-keeping. One commenter objected to any requirement that a governmental broker using other governmental entities as transportation providers document that the transportation is the least costly and most appropriate for each beneficiary because it precludes government social service agencies from being used by the broker to provide transportation.

Response: We do not believe that this documentation requirement will result in significantly more record-keeping. Medicaid laws and regulations, as well as CMS guidance, have always required that there be documentation of medical services that are provided to beneficiaries and that they be made available to CMS upon request. In general, documentation should include verification of eligibility, verification that the service was provided on the date claimed and information about the cost of services. When NEMT is provided as a medical service there should be documentation, not only that the specific ride was provided, but that a Medicaid reimbursable service other than the transportation itself was actually provided on the dates when transportation was claimed. We do not agree that the documentation required when a governmental broker refers to another government entity would prohibit government social service agencies from being used as transportation providers. Given the nature of the client populations served by many of the social service agencies, governmental brokers should not find it difficult to document that the social service agency is the most appropriate and least costly provider of transportation for their client(s).

For the purposes of the final rule, the additional documentation required for the NEMT brokerage would not be significant and should be relatively simple. An annual comparison of the fees paid by Medicaid under the brokerage program for fixed route transportation to the fees charged to the general public for fixed route transportation, and a comparison of the fees paid by Medicaid for public paratransit services to the fees charged to other agencies for comparable public paratransit services, should be all that is necessary.

Comment: Many of the commenters disagreed with the proposed requirement that Medicaid pay no more than the rate charged to the general public for the same type of ride when a governmental broker is a provider of transportation or refers to or subcontracts with another governmental transportation provider. Commenters expressed concern that the actual cost of providing public transportation, particularly publicly provided paratransit rides (that is, door-to-door or curb-to-curb services usually provided to those who are disabled) to the Medicaid population far exceeds the fees charged to the general public because public transit services are subsidized by Federal, State, and local funds, which allows the fares paid by the general public to be set lower than the actual cost of providing the ride. The commenters maintain that prohibiting Medicaid from being charged its fully allocated cost will shift the financial burden of public transit and paratransit trips to State and local entities that fund public transportation. Therefore, the public fare, particularly for paratransit rides, should not be used as a measure to set Medicaid's payment. Medicaid should be charged the fully allocated costs for paratransit rides consistent with this provision and Medicaid's responsibility to assure NEMT.

Many commenters pointed out the fact that the Americans with Disability Act (ADA) requires that States provide disabled members of the public with comparable paratransit services wherever public fixed-route services are offered, and the amount that can be charged to disabled members of the public for comparable public paratransit services may not exceed twice the amount charged to the public for similar fixed-route services. However, these guidelines also say that agencies which purchase publicly-provided paratransit trips for their disabled clients may pay more than the rate charged to disabled individuals receiving a comparable paratransit ride.

Response: In general, States have established rules prohibiting Medicaid from paying more for a covered service than what other third-party payers (for example, health insurers) are charged for the same service. In the case of publicly-provided transportation on fixed routes, while there are other third-party payers (for example, State Human Service agencies) that often cover and reimburse these trips for their clients, we have been informed that such third-parties or agencies generally pay the same amount as the public is charged for these rides. Therefore, we are prohibited from paying more than the public is charged for public transportation on a fixed-route trip.

In the case of publicly-provided paratransit services and rides, based on the comments received and the information provided, we believe that it is appropriate and consistent with current practice for Medicaid to pay

more than the rate charged to disabled individuals for a comparable ride. Based on principles of accounting and financing found in OMB Circular A–87 and section 1902(a)(30) of the Act and 45 CFR 92.36, pertaining to procurements, we believe that Medicaid, through its NEMT program with government brokers, can pay a fare for publicly provided paratransit trips that represents reasonable costs and which is no more than the fare paid for similar paratransit trips by other State Human Services agencies. Therefore, in this final rule we have modified the regulations text at § 440.170(a)(4)(ii)(B)(4)(iii) to require the governmental broker to document that Medicaid is paying for public fixed-route transportation at a rate that is no more than the rate charged to the general public, and no more than the rate charged to other State human services agencies for public paratransit services.

The commenters appear to be concerned about potential limitations on Medicaid payment for public transportation services. The final rule as revised is consistent with current practice and when the State awards a brokerage contract to a governmental transportation broker that is itself a provider of transportation or who refers or subcontracts with another government entity this should not have a significant effect on Medicaid payments to transportation providers. We could have precluded governmental brokers from providing transportation or referring beneficiaries to governmentally-operated transportation altogether. Instead, we provided for safeguards to ensure that governmental brokers operate as independently as non-governmental brokers. We believe that these safeguards will ensure that such transportation will be cost-effective and that the transportation referral will be based on the best interests of the beneficiary, while at the same time meeting the mandate to provide transportation that is the least costly appropriate mode.

Comment: Several commenters disagreed with the requirements of the proposed rule and felt that States were best equipped to design their own systems to prevent the kind of abusive practices and conflicts of interest that might arise when a broker is involved in direct service delivery. These commenters believed that States should be permitted to decide how to institute proper controls that would eliminate any conflicts of interest. A number of commenters said that regional transportation systems and public transportation systems operating as the NEMT broker have the best opportunity and means to coordinate transportation for the benefit of the public. One commenter believed that the State's Department of Transportation and not the Health and Human Services Medicaid program should coordinate Medicaid transportation.

Response: States have broad flexibility to construct an array of NEMT programs that meet each State's diverse needs in terms of geography, transportation infrastructure, and targeted populations, and this final rule preserves this flexibility. However, Medicaid NEMT programs have long been identified by State and Federal Inspector General Reports (for example, HHS, OEI–04095–00 140) as having a high potential for fraud and abuse. As a means of reducing the risk of fraudulent and abusive practices that result in unnecessary or inappropriate use of Medicaid transportation and the loss of millions of Medicaid dollars, the statute specifies that certain provisions be included in the contract between the State and the NEMT broker. The statute also directs us to establish prohibitions on broker referrals and conflict of interest. As a result we have implemented the contract requirements and the prohibitions as provided for in statute.

Comment: One commenter stated that the proposed rule prohibited non-profit transportation providers from being paid more than a governmental broker.

Response: We assume the commenter intended to speak about how the proposed rule prohibited non-profit brokers from being paid more than a governmental broker and therefore believe the commenter misunderstood how the proposed rule distinguishes between two types of brokers, governmental and non-governmental. There is no restriction on a non-profit broker that is not a governmental entity from negotiating rates with public transportation providers.

Comment: Several commenters said the language requiring the contract with a governmental broker to ''provide for payment that does not exceed actual costs calculated as a distinct unit, excluding personnel or other costs shared with or allocated from parent or related entities,'' is ambiguous and can be read two ways, either to include or exclude these costs in the final analysis. Several commenters opposed requiring the public entity broker to be a distinct governmental unit. One commenter expressed the need for further clarification of the requirement that a public broker be a distinct governmental unit and was concerned that the brokerage function would be required to be devoted to only Medicaid-funded transportation, which is directly contrary to the policies established under EO 13330. Another commenter believed that this language was too restrictive and would potentially limit the number of entities that would be eligible to bid.

Response: We agree that this sentence is confusing. Therefore, we have amended this final rule by making it clear, at § 440.170(a)(4)(ii)(B)(4)(i), that if the government broker wishes to be excepted from the self-referral prohibition, the government broker's contract with the State Medicaid agency must specify that the government broker will not charge the Medicaid agency for any personnel or other costs that are shared with, or allocated from, parent or related governmental entities. We expect the governmental broker to maintain an accounting system as though it were a distinct unit, such that all funds allocated to the Medicaid brokerage program and all costs charged to the brokerage program will be completely separate from any other program. Costs that are shared with or allocated from other governmental entities will not be paid by Medicaid.

Comment: One commenter said that the proposed rule does not make allowances for currently existing models that meet the financial, oversight, and contracting requirements of the proposed rule. Another commenter wrote that the proposed rule failed to consider any best practices already in place.

Response: States with existing NEMT brokerage models that do not meet all of the requirements of the DRA and this final rule have other options available, such as obtaining 1915(b) waiver authority or providing NEMT as an administrative expense. The 1915(b) waiver authority process does not prohibit the broker from self-referring nor does it require that the broker be selected through competitive bidding. Providing NEMT as an administrative expense provides States with the greatest flexibility in designing their program.

Comment: One commenter noted that the proposed rule did not mandate provision of bus passes or other fare media for those Medicaid recipients who are able to use public transportation, while another commenter contended that bus passes were not addressed at all in the proposed rule. One commenter suggested that if a Medicaid trip were directed by a broker to a bus, a transit provider should be reimbursed by Medicaid for the cost of a monthly bus pass whether the cost is higher or lower

than the fare for a single trip on the same bus because the pass could be used indefinitely during the month. Several commenters also pointed out that mileage reimbursement was not specifically listed as a transportation service and the proposed rule was unclear as to whether the State could continue to provide this option without securing CMS approval. One commenter requested that CMS specify in the final rule that mileage reimbursement is permitted.

Response: In designing a NEMT brokerage program, States have the option to direct the broker to include bus passes and mileage reimbursement, or to allow the broker to determine which payment methodologies it will use to reimburse for transportation services, including mileage reimbursement and bus passes. Since public transportation is generally the least costly method of transporting beneficiaries, we would expect that the broker would first determine if the physical condition of the beneficiary allows them to use public fixed route transportation before scheduling a more costly paratransit service. However, when bus or transit passes are being considered as a method of paying for trips on public transportation, Medicaid cost effectiveness rules outlined in a December 26, 1996 State Medicaid Director Letter require that the cost of the bus pass must be compared to, and may not exceed, the aggregate cost of the individual trips that will be taken by the beneficiary to access Medicaid providers during that month and on the same bus.

Comment: One commenter stated that because this regulation will shift costs to States and local governments, CMS should examine the proposed rule in the context of the recently published proposed rule, ''Medicaid Program; Elimination of Reimbursement Under Medicaid for School Administration Expenditures and Costs Related to Transportation of School-Age Children Between Home and School'' (72 FR 51397) (September 7, 2007) which would eliminate Medicaid reimbursement for administrative costs related to school based transportation. The commenter indicated that the school-based transportation proposed rule is significantly related to this proposed rule because it would also shift a significant additional financial burden to State and local governments, and local transit agencies.

Response: While we understand the commenter's concerns about the proposed changes to Medicaid funding of school-based transportation, we believe it is only tangentially related to NEMT.

Comment: Several commenters felt that CMS should be more prescriptive about the quality, qualifications, operations standards, and State monitoring of brokers and beneficiary due process rights, and that the proposed rule provided no specificity or guidance on how States should provide and track oversight of the broker. One commenter said that CMS failed to require States to ensure that brokers offered the most appropriate and least costly ride, and that CMS should amend the regulation by adding a reference to 42 CFR 440.230, and also include the requirement that States provide in the State plan a description of the State's specific requirements for the broker. Another commenter provided the following list of requirements that should be included in the final rule: (1) Providers should prove financial stability; (2) provider vehicles should pass rigid vehicle inspections; (3) all providers should be required to carry insurance coverage that is equal to the coverage required for State and local commercial carriers; (4) all providers should be required to have a comprehensive driver training program; (5) providers should be required to meet all applicable Federal, State, and local licensing requirements; (6) companies providing Medicaid transportation should have experience and expertise in providing quality passenger transportation; and (7) Medicaid agency oversight should include annual inspections.

Response: We believe that States are in the best position to design their NEMT brokerage program and oversight procedures, and we expect States to set specific operations standards that at a minimum include: Quality standards for vehicle safety; staff competency; timeliness; access standards; licensing requirements; and grievance procedures. We also expect States to design and implement oversight procedures as required and outlined in the regulations text of this final rule at § 440.170(a)(4)(i)(B). The specific criteria for providers provided by the commenter presents a comprehensive guide and we expect States to include all of these in their oversight of brokers and the brokerage program. We believe that to be more prescriptive in this final rule would limit the flexibility that States need in order to develop their Medicaid transportation brokerage programs.

Section 1902(a)(30) of the Act requires that all Medicaid services be administered consistent with efficiency, economy, and quality of care and we interpret quality to include timeliness. The proposed rule at § 440.170(a)(4)(ii)(D) also requires the brokers to provide the most appropriate and cost-effective means of transportation for each beneficiary. We therefore expect the broker to provide each individual beneficiary with the most appropriate and cost-effective means of transportation and to provide that transportation in a timely fashion so that beneficiaries do not miss scheduled medical appointments. Because it is important that beneficiaries arrive at medical appointments in a timely fashion and that they not be subjected to excessively long waiting periods to return home, in the final rule we have revised the text at § 440.170(a)(4)(i)(B) to require the broker to also have oversight procedures to ensure that transportation is timely and at § 440.170(a)(4)(i)(C) we modified the regulations text to include the requirement that the State regularly audit the timeliness of transportation provided through the brokerage program.

We do not understand the commenters' suggestion that we amend the regulation by adding a reference to § 440.230, since this particular citation discusses the amount, duration, and scope of covered services under the State plan, and we do not believe it to be relevant. We believe the commenter may have thought that utilization control under § 440.230(d) included regulatory oversight.

Comment: One commenter stated that the terms ''broker and brokerage'' are misnomers and suggested that the terminology that should be used is ''transportation program'' or ''transportation services.''

Response: In this final rule we did not replace the terms ''broker and brokerage'' with ''transportation program'' or ''transportation services'' because the statute specifically uses ''broker and brokerage'' and, therefore clearly provides States with the option to establish a transportation brokerage program under the State plan authority. We understand that NEMT brokerage programs may vary from State to State. However, the most fundamental functions of a NEMT broker are to be a single point of contact for beneficiaries to request transportation assistance, and to directly arrange the least costly and most appropriate type of transportation for each beneficiary.

Comment: A number of commenters requested that in the final rule we clarify several terms used in the proposed rule. One commenter asked CMS to clarify the terms ''competent'' and ''courteous,'' while another said

that use of the definition of ''rural area'' found at § 412.62(f) would cause confusion, and that CMS should instead use the term ''non-urbanized area'' as defined in Federal transit laws.

Response: The statute allows both the State and the broker to take responsibility for ensuring that transportation is provided in a competent and courteous manner. In considering whether to define these terms in the final rule, we concluded that States, working with the broker, must determine the competency and courtesy of transport services and staff.

We understand that some commenters believe it would be less confusing if we replaced the term ''rural area'' with ''non-urbanized area'' and use the Federal Transit Administration definition. However, whenever possible, Medicaid regulations have maintained a long history of being consistent with Medicare regulations. For the purposes of this final rule the definition of ''rural area'' as defined at § 412.62(f)(1)(iii) will remain consistent with the definition as exists in the Medicare program.

Comment: Two commenters said that our proposed definition of ''secured transportation'' is unclear and must be clarified. Moreover, one commenter said that as written in the preamble to the proposed rule, it appears that standard airbags in a sedan would qualify, and if the intent of CMS is to address vehicle standards, including wheelchair security and occupant restraints such as those contained in 49 CFR 38.23(d), the regulation should so specify.

Response: In the proposed rule we requested comments on the definition of ''secured transportation'' but received only two comments. These comments expressed the need for clarification and one suggested that we adopt 49 CFR 38.23(d) as the definition of secured transportation if our intent was to define vehicle standards. In requesting comments on the definition of ''secured transportation'' it was not our intent to solicit comments on how to define vehicle standards. We therefore believe the definition in the proposed rule is sufficiently general to permit the State ample flexibility in the design of their brokerage program and have not changed this definition in the final rule.

Comment: One commenter, representing a State, said that some States delegate responsibility for NEMT to multiple regions or counties within the State, and that the rule should be amended to specifically allow a State to submit and receive State Plan approval of a general brokerage program template, including contract language, that would be used by each county or subdivision for implementing individual broker arrangements. Approval of such a template would eliminate the need for CMS to approve each individual brokerage program regardless of whether it was included in the initial SPA or added at a later date.

Response: We recognize that some States have chosen to delegate responsibility for the NEMT brokerage program to individual counties or regions of the State rather than contracting with a state-wide broker. In this model, each county or region operates a separate brokerage program that meets the needs of its beneficiaries, and each brokerage program may vary from area to area within the State. We believe that under this type of model we are obligated to review and approve each separate brokerage program in order to ensure that no conflict of interest exists in any of the various brokerages within the State and that each brokerage program complies with the other statutory and regulatory requirements of a brokerage program.

Comment: Several commenters said that the requirement that government entities and public transportation operators must compete in a competitive bidding process on the same terms as non-governmental entities conflicted with current State laws that allow government entities the right of first refusal. They believed that requiring governmental entities to compete on the same terms as non-governmental entities would create an additional burden just to avoid the perception that there is some inherent conflict of interest for governmental transportation providers that operate as a broker.

Response: While some States may have laws that allow governmental entities the right of first refusal, it is important to note that Section 6083 of the DRA expressly requires competitive bidding, and it did not specifically exempt State and local bodies that wish to serve as brokers from being selected through a fair and open competitive bidding process. We proposed to adopt the applicable provisions of the methodology for competitive bidding set out at 45 CFR 92.36 and do so in the final rule. We are adopting those provisions of 92.36 applicable to the competitive bidding program set out at 92.36(b)–(i). However, we note that we are excluding 92.36(a), which does not set out competitive bidding standards.

Comment: One commenter said that the regulation mirrors the DRA provisions in which the general Medicaid principles of freedom of choice, comparability, and state-wideness do not apply and that both the statute and the proposed rule contravene the intent of the Medicaid program by granting the State the authority to offer a higher level of service to some Medicaid beneficiaries but not to all.

Response: The statute provides that NEMT brokerage programs be implemented without regard to freedom of choice, comparability, and state-wideness in order to allow States to use competitive bidding to identify and select the most cost-effective and efficient NEMT broker. Because NEMT needs may differ from region to region it may be necessary to offer certain services in one area of the State but not in another. In creating this new option for States, the statute provides States with the greatest flexibility to customize their brokerage programs to meet the needs of all beneficiaries in all areas of the State, and for States to take advantage of the cost saving measures that NEMT brokers can offer. We note that for a number of years States have implemented NEMT brokerage programs under 1915(b) waiver authority in selected areas of the State without regard to freedom of choice, comparability, and or state-wideness. Both the statute and this final regulation make it possible to provide NEMT through a broker without regard to freedom of choice, comparability, and state-wideness, while maintaining the highest level of services for all Medicaid beneficiaries.

Comment: One commenter believed that the requirement that the beneficiary have no other means of transportation found in § 440.170(a)(4) of the proposed rule could significantly limit the number of Medicaid-enrolled individuals who could benefit from the Medicaid NEMT program. The commenter believed that CMS failed to take into account beneficiaries who normally have another means of transportation but cannot utilize it due to their current medical condition, and that this failure could lead to these beneficiaries being denied transportation assistance. The commenter requested that we amend the language to read ''that the beneficiary must have no other available'' means of transportation.

Response: We did not adopt in this final rule the commenter's suggestion that we amend the language in § 440.170(a)(4) by adding the word ''available,'' because we believe that States and brokers understand that they must take into consideration the beneficiary's physical condition when determining if the beneficiary has another means of getting to and from a medical service.

Comment: One commenter requested that we clarify treatment of a federally qualified health center (FQHC) with regard to NEMT services because FQHC services, including transportation, are mandatory and the State can include transportation costs in the Prospective Payment System (PPS) per visit payment or in its Alternative Payment Methodology (APM) per visit payment. The commenter further stated that a State's decision to contract with a broker does not eliminate the legal obligation to allow an FQHC to continue to provide and be reimbursed for transportation through the PPS or APM payment.

Response: In agreeing with the commenter we wish to clarify that a State's decision to establish a NEMT brokerage program does not preclude the State from allowing an FQHC to continue to provide for and be paid for transportation as part of the Prospective Payment System per visit payment or as part of the Alternative Payment Methodology per visit payment. We assume that a State's request for proposal would indicate this in accordance with the State's policy.

Comment: The August 24, 2007 proposed rule proposed an exception to the prohibition on self-referral for governmental brokers that prohibited Medicaid from paying more than the general public rate for public transit services. Many of the State transportation agencies that commented believed the regulation would create an unfunded mandate by shifting costs to State and local governments. These commenters contended that even though the general public fare is heavily subsidized by State and Federal funds it still does not accurately represent the full cost of providing paratransit services. The commenters also said the increased financial burden on States that would be created should Medicaid not pay the full cost of a paratransit trip, along with the additional capital costs that would be needed to fund the resulting increased demand for paratransit services, would exceed the $120 million dollar threshold for a major rule. Many commenters disagreed that the proposed rule would have no consequential effect on State, local and tribal governments and requested that CMS either reconsider this requirement and allow a Medicaid governmental broker to pay the fully allocated cost for public paratransit, or withdraw the regulation and perform and make publicly available a detailed study of the number of trips likely to be shifted to local responsibility, as well as the financial impact of those trips.

Response: We considered all of the comments on the governmental broker not paying more than the public rate and have revised § 440.170(a)(4)(ii)(B)(4)(iii) in this final rule so as to now require that in the case of a governmental broker, the rate paid by Medicaid for publicly provided fixed route transportation be no more than the rate paid by the public, and the rate paid by Medicaid for public paratransit represent reasonable costs and be comparable to the rate paid for similar paratransit trips by other State human services agencies. We therefore believe that this final rule does not create an unfunded mandate for States, localities, tribal governments, or the private sector.

Comment: In the proposed rule two commenters suggested that the collection of information requirements were significantly understated. One commenter said that according to their experience it took five hours to initially complete the State plan amendment preprint, and an additional nine hours to respond in writing to requests from CMS for additional information. Another commenter noted that the level of documentation required for governmental entities that are brokers is extensive, costly, and unnecessarily duplicative of the annual monitoring of expenditures that is required by the Department of Transportation.

Response: In order to minimize the amount of time needed to complete a State plan amendment establishing a NEMT brokerage program, we designed a five-page preprint that allows the State to complete almost all of the sections by checking a box next to each answer. We expect that prior to completing the preprint a State will have fully developed the information that describes the brokerage program and can insert or attach this information to the preprint. With that assumption in mind, we estimated that it would take no more than 12 minutes to check off the appropriate boxes and to insert or attach any already created information concerning the NEMT brokerage program that is necessary to complete the State plan amendment.

With regard to additional documentation requirements created by the proposed rule, Medicaid laws and regulations, as well as CMS guidance, have always required States to maintain documentation of the medical services that are provided to beneficiaries. The requirement in the proposed rule that States, through the broker, document each specific ride that was provided and that a Medicaid reimbursable service other than transportation was actually provided on the date transportation was provided is not a new collection of information.

In this final rule we revised the requirement that governmental brokers document that Medicaid paid no more for public transportation than the rate charged to the general public and have instead included a requirement that in the case of a governmental broker, there be documentation that Medicaid paid no more for public fixed route transportation than the general public, and no more for public paratransit services than the rate charged to other human services agencies for a comparable ride. We believe this documentation requirement to be relatively simple and to require no more than an annual comparison of the fees paid by Medicaid under the brokerage program to the fees charged to the general public for fixed route transportation, and a comparison of the fees paid by Medicaid (under the broker program) for public paratransit services to the fees paid by other human services agencies for comparable public paratransit services. We do not believe that the documentation requirement for government brokers set forth in the proposed rule represents any substantial additional time and cost. Therefore, we have not revised the collection of information estimate in this final rule.

IV. Provisions of the Final Regulations

We are maintaining the majority of the provisions set out in the August 24, 2007 proposed rule, with several exceptions. The provisions of this final rule that differ from the proposed rule with comment period are as follows:

(1) We have modified the regulations text at § 440.170(a)(4)(i)(B) by adding the additional requirement that the broker have oversight procedures to monitor and ensure the timeliness of the transportation provided to beneficiaries.

(2) We have modified the regulations text at § 440.170(a)(4)(ii)(B)(4) by removing the requirement that the broker be a ''distinct government entity.'' However, in § 440.170(a)(4)(ii)(B)(4)(i), we continue to expect the governmental broker to maintain an accounting system as though it were a distinct unit, such that all funds allocated to the Medicaid brokerage program and all costs charged to the brokerage program will be completely separate from any other program. We have also clarified that costs shared with other governmental entities cannot be allocated to the brokerage program.

(3) We have modified the regulations text at § 440.170(a)(4)(ii)(B)(4)(iii) by removing the requirement that the broker document that the Medicaid

program is paying no more than the rate charged to the general public and replacing it with the requirement that the broker document that the Medicaid program is paying no more than the rate charged to the general public for public fixed-route transportation and no more than the rate charged to other agencies for comparable public paratransit services.

(4) We have modified the regulations text at § 440.170(a)(4)(i)(C) by adding the additional requirement that the State provide oversight and regularly audit the broker to ensure the timeliness of the transportation provided to beneficiaries.

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 30-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506I(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We solicited public comment on each of these issues for the following sections of this document that contain information collection requirements:

State Option To Establish a Non-Emergency Medical Transportation Brokerage Program [§ 440.170(a)]

Section § 440.170(a) provides States with the option to submit a State plan amendment (SPA) to establish a non-emergency medical transportation (NEMT) brokerage program. To effectuate this option, States must submit an amendment to their existing State plan. CMS has provided States with a letter providing guidance on this provision and the implementation of the DRA, and an associated SPA preprint for use by the States to modify their Medicaid State plan should they choose to implement this option.

The preprint is a total of 5 pages and we estimate that it will take no more than 12 minutes for a State to actually complete and submit the template to CMS. The potential number of respondents is 56 (50 States, the District of Columbia, and five territories); however, we do not expect the territories or all 50 states to respond. We estimate that only five States will submit annually. Once approved, the State will not need to resubmit unless it is materially changing the brokerage program. The burden associated with this requirement is approved under OMB #0938–0993. We submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, *Attn.:* Melissa Musotto, CMS–2234–F, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–1850.

Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, *Attn:* CMS Desk Officer, CMS–2234–F, Fax (202) 395–6974.

VI. Regulatory Impact Statement

We 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. 104–4), Executive Order 13132 on Federalism and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) 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 major rules with economically significant effects ($100 million; or more in any 1 year). We estimate that this regulation will have estimated budget savings of $145 million between FY 2008 and FY 2012 due to the implementation of section 6083 of the Deficit Reduction Act of 2005. No single year will exceed $100 million, therefore, this rule will 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 businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6.5 million to $30.5 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 the RFA because we have determined, and the Secretary certifies, 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 604 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, and the Secretary certifies, 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 whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. That threshold level is currently approximately $127 million. This rule would have no consequential effect on State, local, or tribal governments in the aggregate, or by the private sector, of $127 million.

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. Since this regulation would not impose any costs on State or local governments, the requirements of E.O. 13132 are not applicable.

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

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), as amended.

■ 2. A new authority citation is added in numerical order to § 440.1 to read as follows:

§ 440.1 Basis and purpose.

* * * * *

1902(a)(70), State option to establish a non-emergency medical transportation program.

* * * * *

■ 3. Section 440.170 is amended by revising paragraph (a)(2) and adding new paragraph (a)(4) to read as follows:

§ 440.170 Any other medical care or remedial care recognized under State law and specified by the Secretary.

(a) * * *

(2) Except as provided in paragraph (a)(4), transportation, as defined in this section, is furnished only by a provider to whom a direct vendor payment can appropriately be made by the agency.

* * * * *

(4) Non-emergency medical transportation brokerage program. At the option of the State, and notwithstanding § 431.50 (statewide operation) and § 431.51 (freedom of choice of providers) of this chapter and § 440.240 (comparability of services for groups), a State plan may provide for the establishment of a non-emergency medical transportation brokerage program in order to more cost-effectively provide non-emergency medical transportation services for individuals eligible for medical assistance under the State plan who need access to medical care or services, and have no other means of transportation. These transportation services include wheelchair vans, taxis, stretcher cars, bus passes and tickets, secured transportation containing an occupant protection system that addresses safety needs of disabled or special needs individuals, and other forms of transportation otherwise covered under the state plan.

(i) Non-emergency medical transportation services may be provided under contract with individuals or entities that meet the following requirements:

(A) Is selected through a competitive bidding process that is consistent with 45 CFR 92.36(b) through (i) and is based on the State's evaluation of the broker's experience, performance, references, resources, qualifications, and costs.

(B) Has oversight procedures to monitor beneficiary access and complaints and ensure that transportation is timely and that transport personnel are licensed, qualified, competent, and courteous.

(C) Is subject to regular auditing and oversight by the State in order to ensure the quality and timeliness of the transportation services provided and the adequacy of beneficiary access to medical care and services.

(D) Is subject to a written contract that imposes the requirements related to prohibitions on referrals and conflicts of interest described at § 440.170(a)(4)(ii), and provides for the broker to be liable for the full cost of services resulting from a prohibited referral or subcontract.

(ii) Federal financial participation is available at the medical assistance rate for the cost of a written brokerage contract that:

(A) Except as provided in paragraph (a)(4)(ii)(B) of this section, prohibits the broker (including contractors, owners, investors, Boards of Directors, corporate officers, and employees) from providing non-emergency medical transportation services or making a referral or subcontracting to a transportation service provider if:

(*1*) The broker has a financial relationship with the transportation provider as defined at § 411.354(a) of this chapter with ''transportation broker'' substituted for ''physician'' and ''non-emergency transportation'' substituted for ''DHS''; or

(*2*) The broker has an immediate family member, as defined at § 411.351 of this chapter, that has a direct or indirect financial relationship with the transportation provider, with the term ''transportation broker'' substituted for ''physician.''

(B) Exceptions: The prohibitions described at clause (A) of this paragraph do not apply if there is documentation to support the following:

(*1*) Transportation is provided in a rural area, as defined at § 412.62(f), and there is no other available Medicaid participating provider or other provider determined by the State to be qualified except the non-governmental broker.

(*2*) Transportation is so specialized that there is no other available Medicaid participating provider or other provider determined by the State to be qualified except the non-governmental broker.

(*3*) Except for the non-governmental broker, the availability of other Medicaid participating providers or other providers determined by the State to be qualified is insufficient to meet the need for transportation.

(*4*) The broker is a government entity and the individual service is provided by the broker, or is referred to or subcontracted with another government-owned or operated transportation provider generally available in the community, if the following conditions are met:

(*i*) The contract with the broker provides for payment that does not exceed the actual costs calculated as though the broker were a distinct unit, and excludes from these payments any personnel or other costs shared with or allocated from parent or related entities; and the governmental broker maintains an accounting system such that all funds allocated to the Medicaid brokerage program and all costs charged to the brokerage program will be completely separate from any other program;

(*ii*) The broker documents that, with respect to the individual's specific transportation needs, the government provider is the most appropriate and lowest cost alternative; and

(*iii*) The broker documents that the Medicaid program is paying no more for fixed route public transportation than the rate charged to the general public and no more for public paratransit services than the rate charged to other State human services agencies for comparable services.

(C) Transportation providers may not offer or make any payment or other form of remuneration, including any kickback, rebate, cash, gifts, or service in kind to the broker in order to influence referrals or subcontracting for non-emergency medical transportation provided to a Medicaid recipient.

(D) In referring or subcontracting for non-emergency medical transportation with transportation providers, a broker may not withhold necessary non-emergency medical transportation from a Medicaid recipient or provide non-emergency medical transportation that is not the most appropriate and a cost-effective means of transportation for that recipient for the purpose of financial gain, or for any other purpose.

(E) The non-Federal share of all Medicaid payments under the transportation brokerage program must be in compliance with applicable Federal requirements in sections 1902(a)(2) and 1903(w) of the Act, and applicable Federal regulations set forth

at § 433.50 through § 433.74 of this chapter.

* * * * *

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

Dated: April 17, 2008.

Kerry Weems,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: *May 21, 2008.*

Michael O. Leavitt,

Secretary.

Editorial Note: This document was received in the Office of the Federal Register on Wednesday, December 10, 2008.

[FR Doc. E8–29662 Filed 12–15–08; 11:15 am]

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DEPARTMENT OF HOMELAND SECURITY

Transportation Security Administration

49 CFR Parts 1520 and 1580

[Docket No. TSA–2006–26514; Amendment nos. 1520–6, 1580–1]

RIN 1652–AA51

Rail Transportation Security

AGENCY: Transportation Security Administration, DHS.

ACTION: Final rule.

SUMMARY: The Transportation Security Administration (TSA) extends the December 26, 2008 effective date of one section of the final rule entitled ''Rail Transportation Security,'' published in the **Federal Register** on November 26, 2008, 73 FR 72131, until April 1, 2009. This extension of the effective date is to afford affected freight railroad carriers, rail hazardous materials shippers, and rail hazardous materials receivers additional time to conduct training and implement procedures to come into compliance with the chain of custody and control requirements of the rule.

DATES: The effective date of 49 CFR 1580.107 of the final rule published in the **Federal Register** on November 26, 2008, at 73 FR 72131 is delayed until April 1, 2009. The effective date of the amendment to 49 CFR part 1520 and the effective date of all other sections of 49 CFR part 1580 remains December 26, 2008.

FOR FURTHER INFORMATION CONTACT: *For questions related to freight rail security:* Scott Gorton, Transportation Sector Network Management, Freight Rail Security, TSA–28, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6028; telephone (571) 227–1251; facsimile (571) 227–1923; e-mail *freightrailsecurity@dhs.gov*.

For questions related to passenger rail security: Morvarid Zolghadr, Mass Transit and Passenger Rail Security, TSA–28, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6028; telephone (571) 227–2957; e-mail *passengerrailcomments@dhs.gov*.

For questions related to SSI: Andrew E. Colsky, Office of the Special Counselor, SSI Office, TSA–31, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598–6031; telephone (571) 227–3513; facsimile (571) 227–2945; e-mail *SSI@dhs.gov*.

SUPPLEMENTARY INFORMATION: On November 26, 2008, TSA issued its Rail Transportation Security rule. 73 FR 72130. The effective date to comply with all provisions of the final rule was December 26, 2008.

The final rule on rail transportation security included a section to require a secure chain of physical custody for rail cars containing one or more rail security-sensitive materials. *See* 49 CFR 1580.107. On December 11, 2008, the Association of American Railroads and its member freight railroads requested that TSA delay the effective date of this provision. They presented information indicating that the initial 30-day period for compliance did not afford sufficient time for railroad carriers to implement procedures and train their workforce to meet the new regulatory requirement.

TSA recognizes that the affected regulated parties would have significant difficulty in complying with the chain of custody and control requirements in the time specified, and has decided to extend the effective date for compliance with 49 CFR 1580.107 to April 1, 2009.

Issued in Arlington, Virginia, on December 15, 2008.

John Sammon,

Assistant Administrator.

[FR Doc. E8–30156 Filed 12–18–08; 8:45 am]

BILLING CODE 9110–05–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 229

[Docket No. 080407531–8840–02]

RIN 0648–AW68

Taking of Marine Mammals Incidental to Commercial Fishing Operations; Bottlenose Dolphin Take Reduction Plan

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

ACTION: Final rule.

SUMMARY: The National Marine Fisheries Service (NMFS) issues this final rule amending the Bottlenose Dolphin Take Reduction Plan's (BDTRP) implementing regulations by extending, for an additional three years, fishing restrictions expiring on May 26, 2009. This action continues, without modification, current nighttime fishing restrictions of medium mesh gillnets operating in the North Carolina portion of the Winter-Mixed Management Unit during the winter. Medium mesh fishing restrictions are extended for an additional three years to ensure continued conservation of the Western North Atlantic coastal bottlenose dolphin stock, should a directed spiny dogfish fishery reemerge in North Carolina.

DATES: This final rule is effective January 20, 2009.

ADDRESSES: Copies of the proposed rule to amend the BDTRP, the final BDTRP, Environmental Assessment, BDTRT meeting summaries, and background documents can be downloaded from the Take Reduction Plan web site at: *http://www.nmfs.noaa.gov/pr/interactions/trt/bdtrp.htm*.

FOR FURTHER INFORMATION CONTACT: Stacey Carlson, NMFS, Southeast Region, 727–824–5312, *Stacey.Carlson@noaa.gov*; or Melissa Andersen, NMFS, Protected Resources, 301–713–2322, *Melissa.Andersen@noaa.gov*. Individuals who use telecommunications devices for the deaf (TDD) may call the Federal Information Relay Service at 1–800–877–8339 between 8 a.m. and 4 p.m. eastern time, Monday through Friday, excluding Federal holidays.

SUPPLEMENTARY INFORMATION: